

ENGLISH

SCANORA[®] 3Dx

Cone Beam 3D Imaging System

User's Manual

207301 rev. 03 (2012-04)

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User's Manual



Medical Device Directive
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1. Introduction

1.1 The SCANORA® 3Dx

The **SCANORA® 3Dx** is a cone beam computerized tomography x-ray unit.

The **SCANORA® 3Dx** unit (the unit) is part of the **SCANORA® 3Dx system** (the system) that comprises the unit which is connected to a PC (the PC) in which suitable dental imaging software and 3D imaging software have been installed.

All software must conform to the MDD and the relevant legal requirements in the USA.

The unit uses an amorphous silicon flat panel detector for acquiring 3D images and an optional CCD sensor for acquiring panoramic images.

1.2 Intended use

The unit must only be used and operated by qualified healthcare professionals.

The unit must only be used to take 3D and (optional) panoramic images of the dento-maxillo-facial complex and the head and neck areas, including the ear, nose and throat (ENT) areas of the human skull. The unit must not be used to take images of any other part of the human body.

Note that panoramic and 3D exposures should not be used if conventional intraoral radiographic images (bitewing exposures) would suffice.

Note that cone beam computerized tomography images are not adequate for the analysis of soft tissue.

USA only

Caution: Federal law restricts this device to sale by or on the order of a dentist or other qualified professional.

1.3 Imaging programs

3D programs

The following **3D images** can be taken, using either standard or high resolution:

- **50 x 50 mm** (height x diameter), small (**S**) FOV (Field Of View),
- **50 x 100 mm**, small plus (**S+**) FOV
- **80 x 100 mm**, medium (**M**) FOV
- **80 x 165 mm**, medium plus (**M+**) FOV
- **140 x 100 mm**, large (**L**) FOV
- **140 x 165 mm**, large plus (**L+**) FOV

Optional 3D programs:

- **180 x 165 mm**, extra large (**XL**) FOV
- **240 x 165 mm**, extra large plus (**XL+**) FOV

For the optional XL and XL+ images, two 3D images are taken and then combined (stitched) to form a XL or XL+ image.

Scout programs

Scout programs take single exposure image(s) that can be used to verify the position of the 3D image before it is taken.

The scout programs can take a lateral image (Lat) or a anterior-posterior (AP) image or both a lateral and anterior-posterior image.

The sizes of the scout images (height and width) correspond to the sizes of the 3D image (height and diameter) except for the optional XL and XL+ FOVs where the scout images are of the lower part of the 3D image only.

Panoramic programs (Optional)

With the OPTIONAL panoramic sensor the following **panoramic images** can be taken:

- Adult panoramic,
- Child panoramic (reduced width and height)
- Temporomandibular joint (TMJ)
- Five freely selectable partial segments.

1.4 About this manual

This manual describes how to set up and use both the 3D and the 3D pan versions of the **SCANORA® 3Dx** x-ray unit.

Please read this user's manual before operating the unit for the first time.

CAUTION:

It is important to read the warnings and precautions, listed in section 8, before operating the unit for the first time.

It is also important to observe these warnings and precautions whenever the unit is used.

NOTE:

Instructions in this user's manual starting with **PC**: for example:

"1. **PC**: Open a new or existing patient" indicate that the task is carried out from the PC.

Instructions NOT starting with **PC**: for example:

"3. Close the head supports" indicate that the task is carried out from the UNIT.

NOTE:

Before you use the imaging system for the first time, set the system to your requirements. See section 5. System Settings.

1.5 Abbreviations used in this manual

FOV = Field Of View. The cylindrical 3D volume that the unit will take an exposure of.

ROI = Region Of Interest. The anatomical area or region of the patient that you wish to examine.

1.6 Associated documentation

The SCANORA® Workstation Software user's manual.

The user documentation supplied with the 3D viewing software you are using.

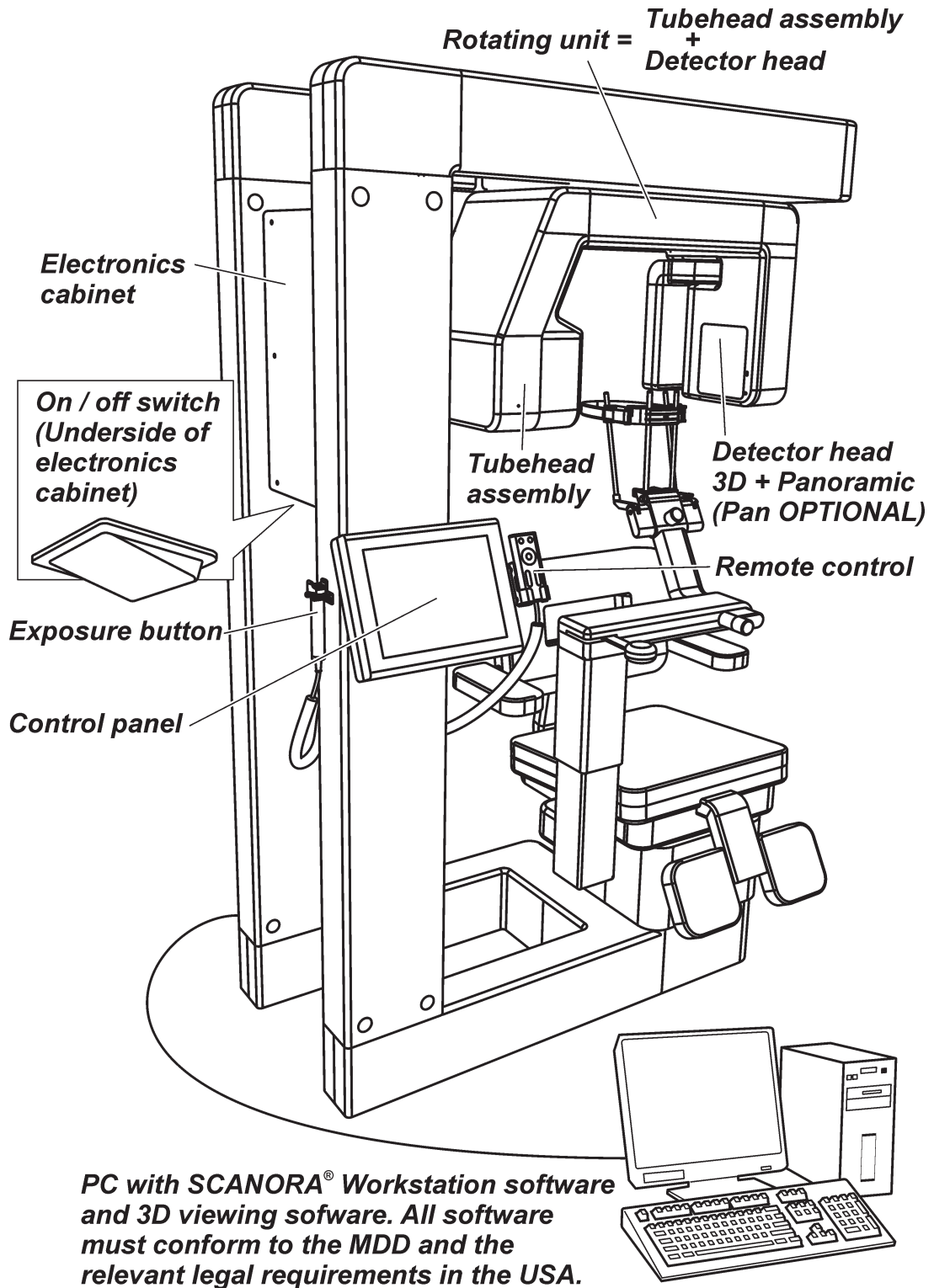
Any applicable (optional) local or national requirements or specifications related to the operation, testing and maintenance of dental x-ray imaging devices and systems.

1.7 About cone beam 3D imaging

During a 3D exposure the tubehead rotates around the patient's head taking a series of 2D images of the selected ROI, 150 to 600 depending upon the 3D program and resolution selected. The 3D imaging software then reconstructs the separate 2D images to form a 3D model (a volume) of the ROI.

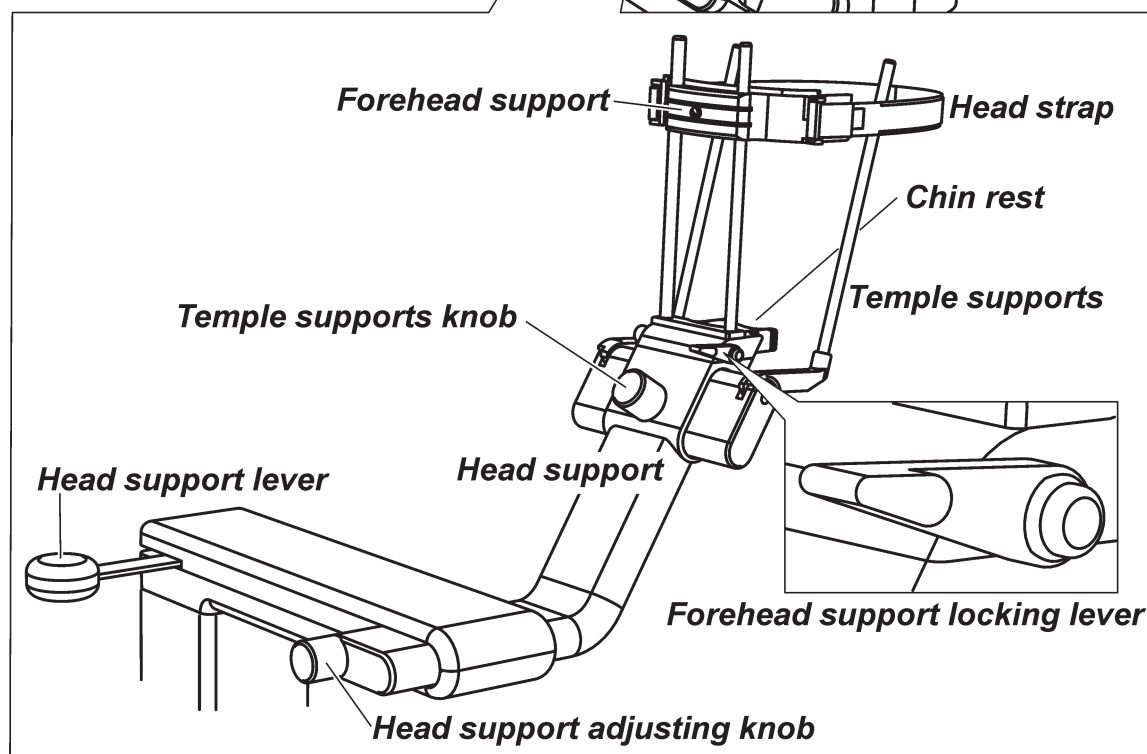
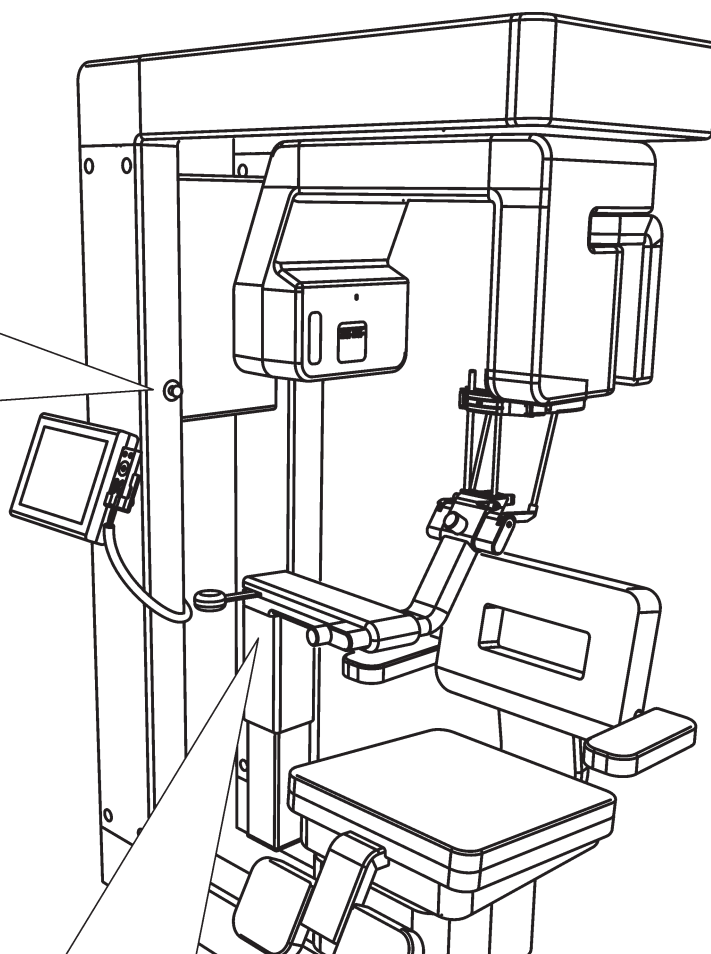
2. The SCANORA® 3Dx

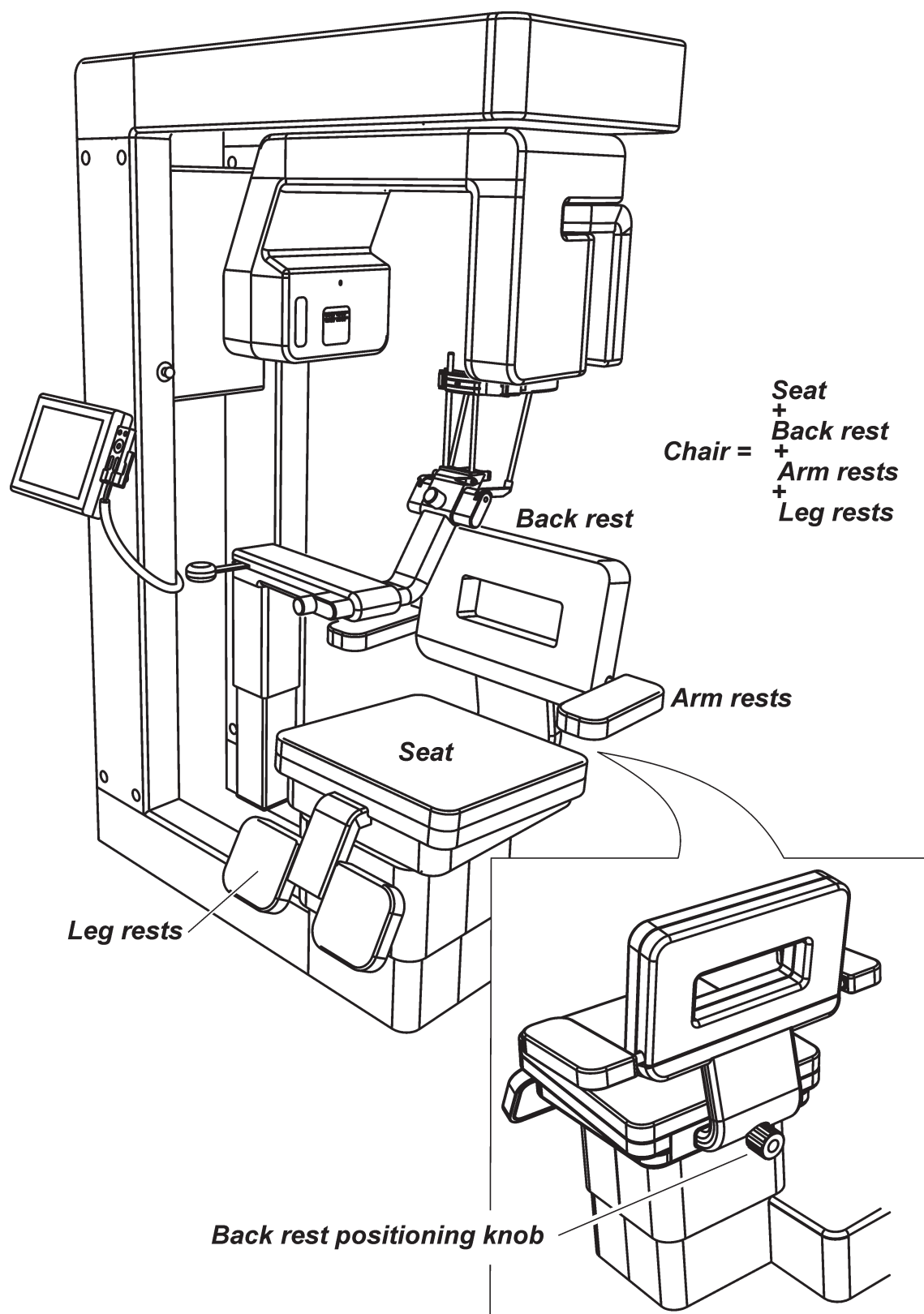
2.1 Main parts and controls



Emergency stop knob

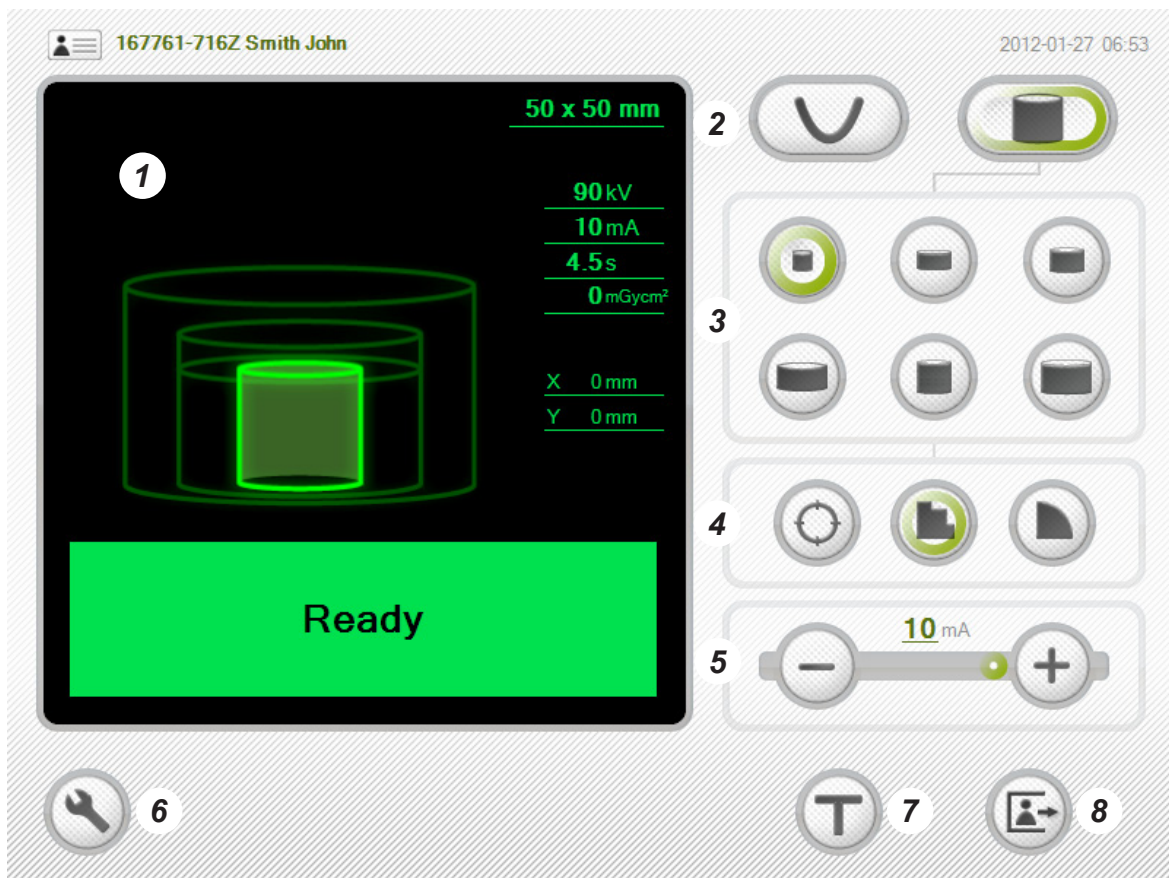
- Press to stop the unit,
- Rotate to release





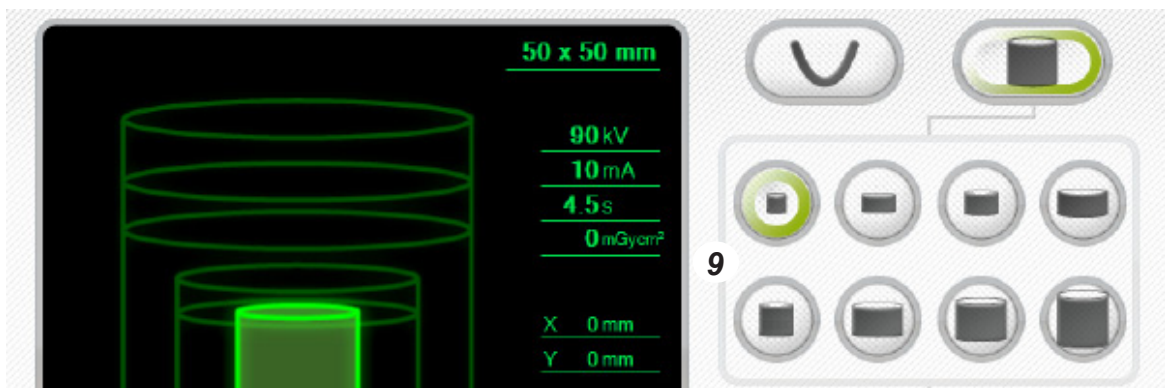
2.2 The control panel

3D display



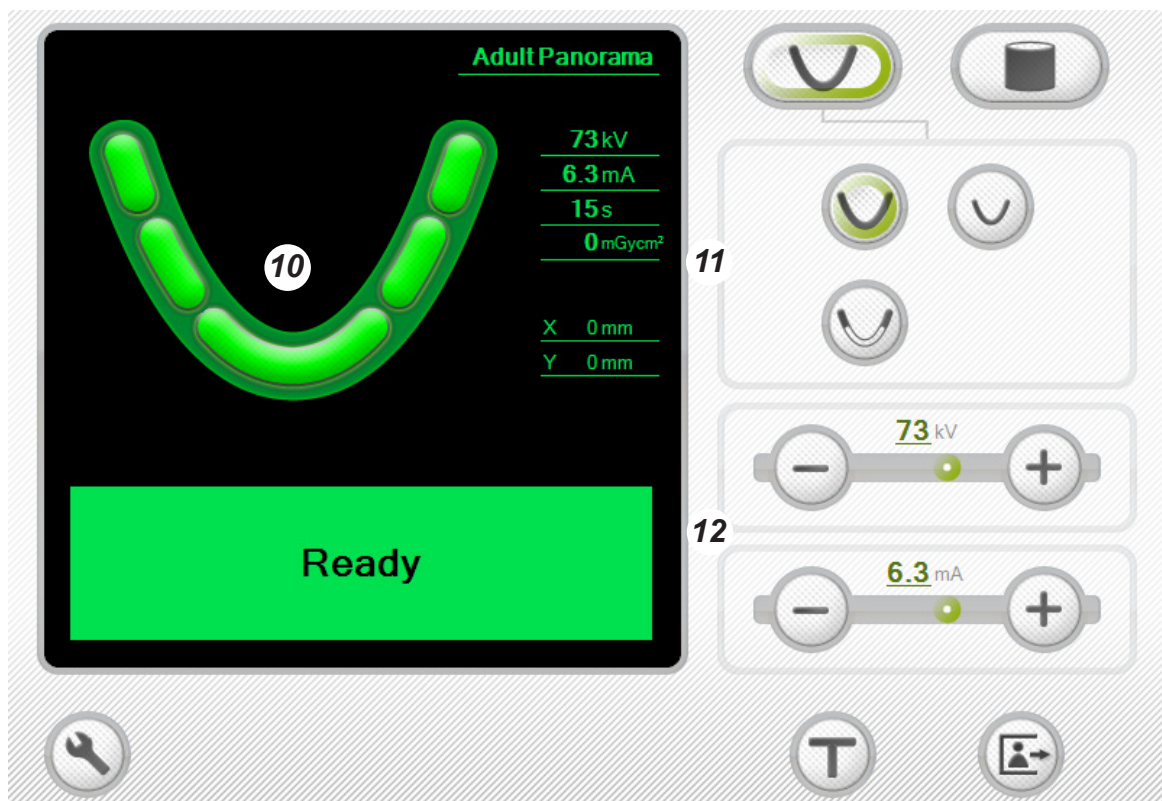
1. *Information window*
2. *Mode buttons (panoramic is optional)*
3. *FOV (Field of View) buttons*
4. *Scout/resolution buttons*
5. *mA buttons.*
6. *Settings button*
7. *Test exposure button*
8. *End study button*

3D (optional) display



9. FOV and XL FOV buttons

Panoramic (optional) display

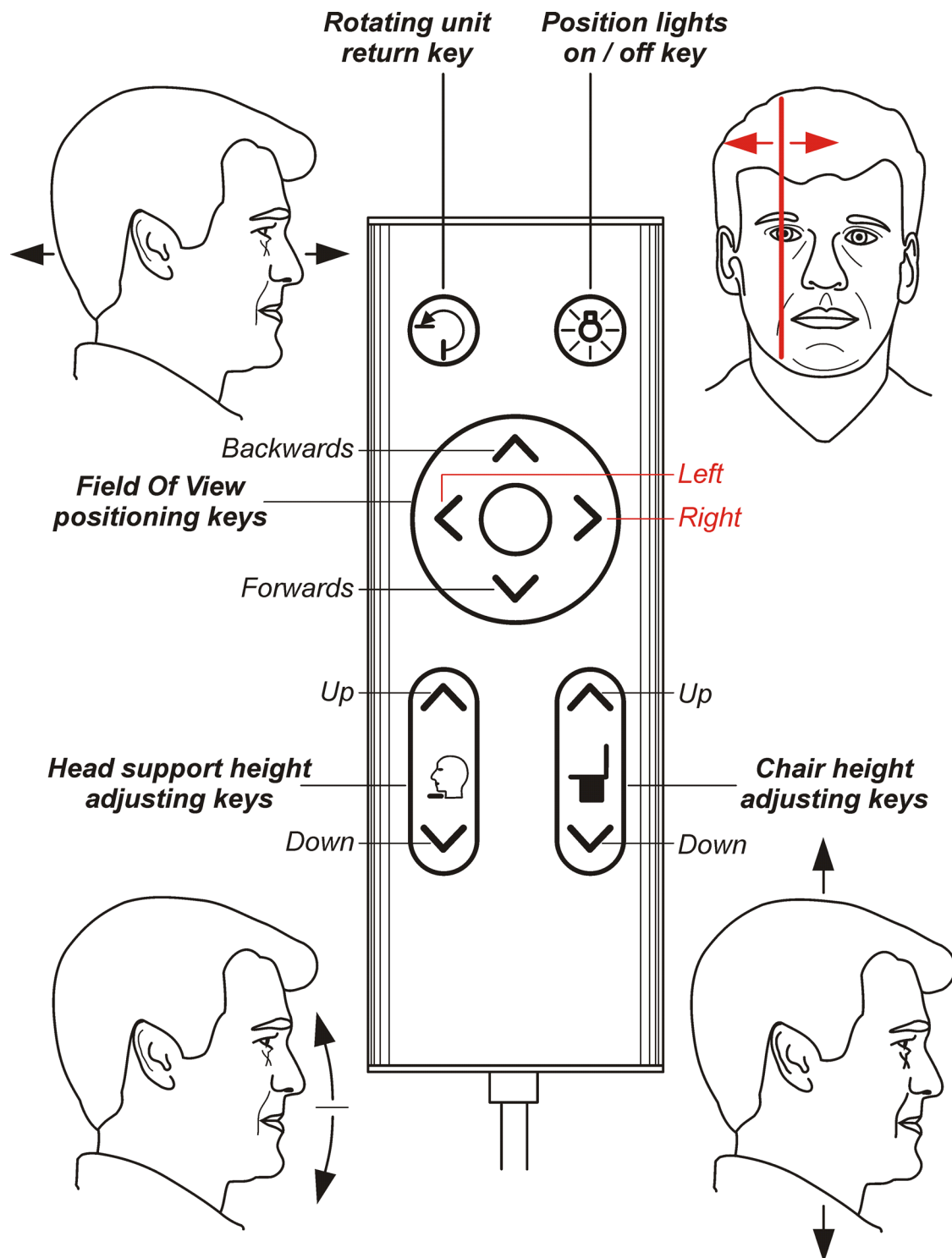


10. Partial panoramic exposure buttons

11. Program buttons

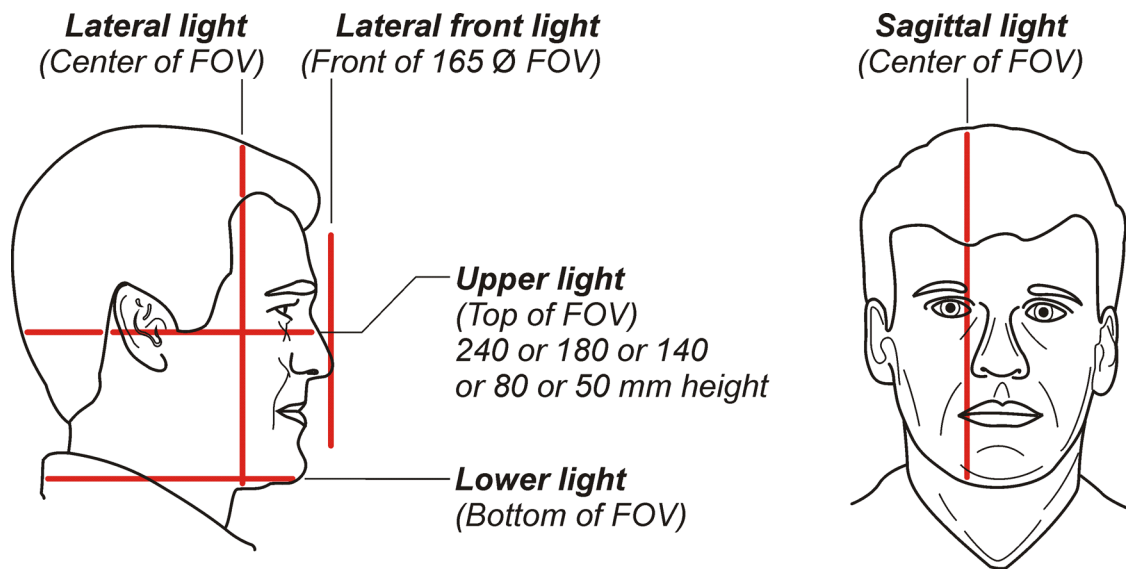
12. kV buttons mA buttons

2.3 Remote control

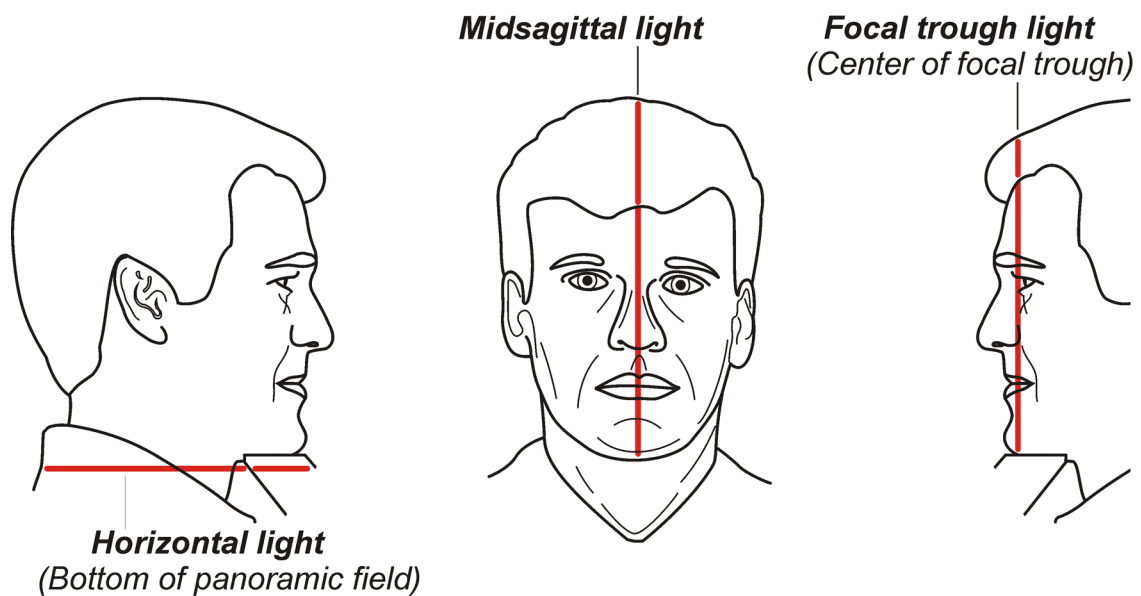


2.4 Patient positioning lights

3D lights

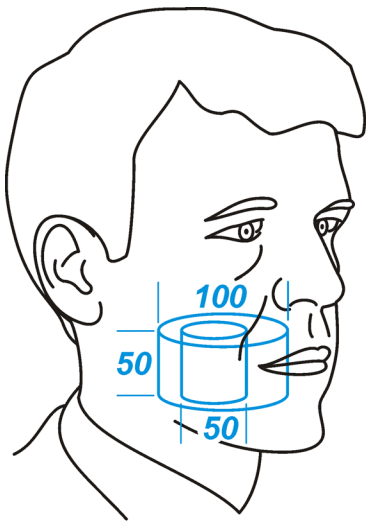


Panoramic lights (Optional)



2.5 Imaging programs

3D programs



50 x 50 mm (height x diameter) small FOV (**S**).

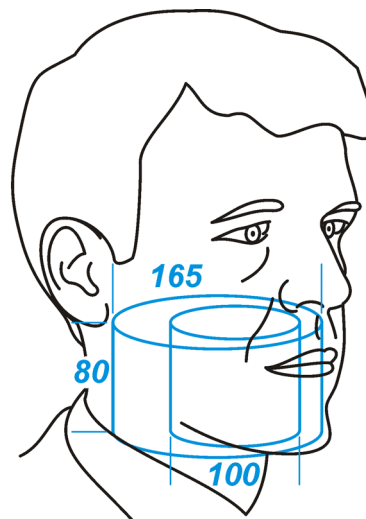
Resolution (voxel size): standard 0.150 mm or high 0.100 mm.

Use: single implants, wisdom teeth, localized dental problems, single TMJ, ear, etc.

50 x 100 mm (height x diameter) small plus FOV (**S+**)

Resolution (voxel size): standard 0.400 mm or high 0.200 mm.

Use: maxilla or mandible, implants for one jaw, etc.



80 x 100 mm (height x diameter) medium FOV (**M**)

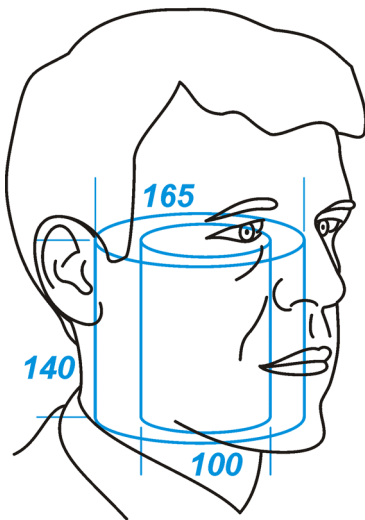
Resolution (voxel size): standard 0.250 mm or high 0.150 mm.

Use: maxilla and mandible, implants for both jaws, etc.

80 x 165 mm (height x diameter) medium plus FOV (**M+**)

Resolution (voxel size): standard 0.350 mm or high 0.150 mm.

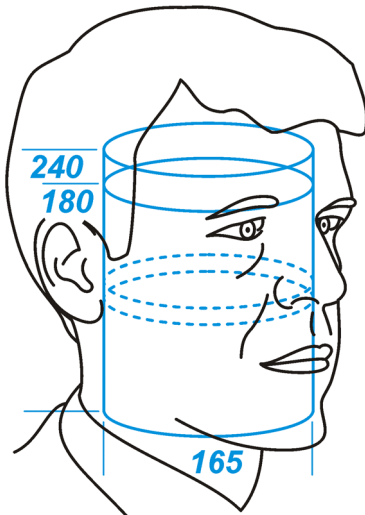
Use: TMJs and ears



140 x 100 mm (height x diameter) large FOV (**L**).
Resolution (voxel size): standard 0.350 mm or high 0.250 mm.
Use: sinuses

140 x 165 mm (height x diameter) large plus FOV (**L+**).
Resolution voxel size: standard 0.300 mm or high 0.200 mm.
Use: sinuses, both TMJs, both temporal bones, ENT, etc.

Optional 3D programs



180 x 165 mm (height x diameter) extra large FOV (**XL**).
Resolution (voxel size): standard 0.500 mm or high 0.300 mm.
Use: both jaws, sinuses, both TMJs, both temporal bones, ENT, etc.

240 x 165 mm (height x diameter) extra large plus FOV (**XL+**).
Resolution (voxel size): standard 0.500 mm or high 0.300 mm.
Use: facial surgery planning and control, traumatology, ortho, etc.

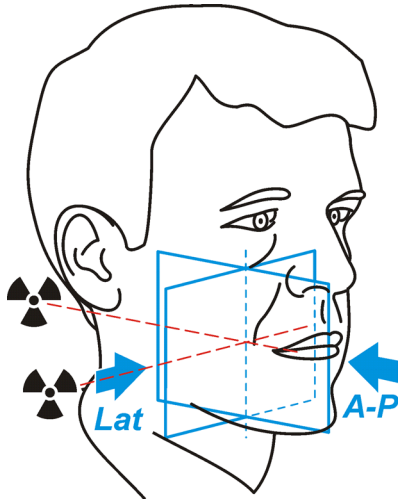
Scout programs

The scout programs are used to verify the position of the 3D FOVs.

Each scout program takes a lateral image or a anterior-posterior image or both lateral and anterior-posterior images of the corresponding 3D FOV.

NOTE:

The lateral exposure is taken from the right-hand side of the patient and the anterior-posterior image from the rear.



50 x 50 mm (height x width) scout images.

For verifying the position of the 50 x 50 mm 3D small FOV.

50 x 100 mm (height x width) scout images.

For verifying the position of the 50 x 100 mm 3D small plus FOV.

80 x 100 mm (height x width) scout images.

For verifying the position of the 80 x 100 mm 3D medium FOV.

80 x 165 mm (height x width) scout images.

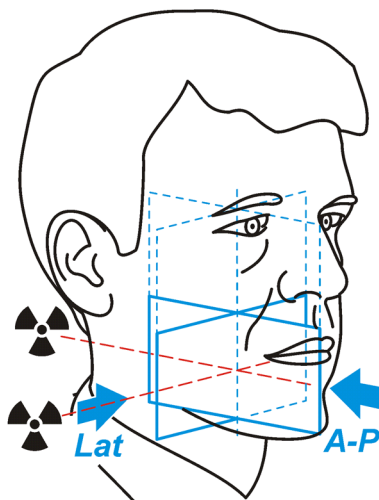
For verifying the position of the 80 x 165 mm 3D medium plus FOV.

140 x 100 mm (height x width) scout images.

For verifying the position of the 140 x 100 mm 3D large FOV.

140 x 165 mm (height x width) scout images.

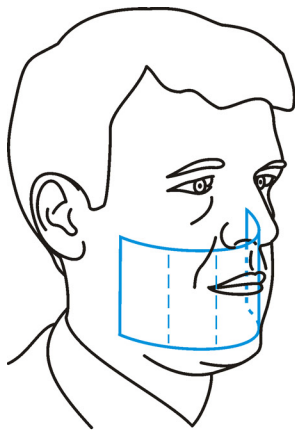
For verifying the position of the 140 x 165 mm 3D large plus FOV.



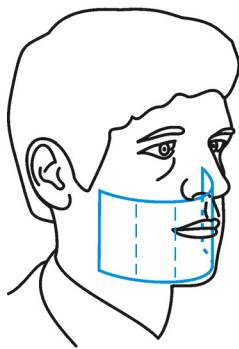
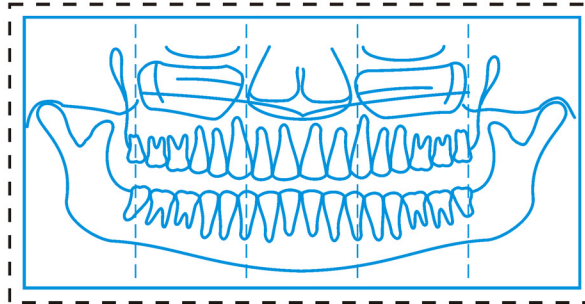
140 x 165 (height x width) for verifying the positions of the optional 180 x 165 mm 3D XL FOV and the 240 x 165 mm 3D XL plus FOV.

The scout image or images are of the **lower part** of the 3D FOVs.

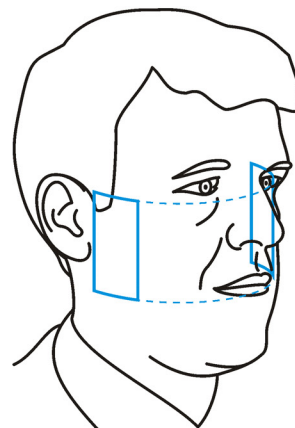
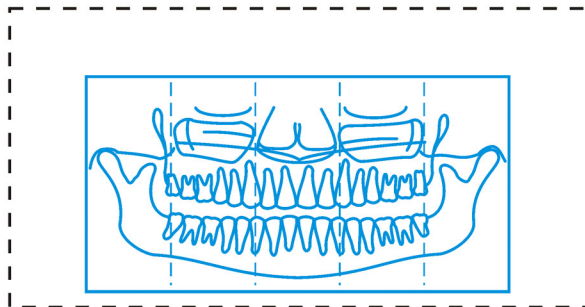
Panoramic programs (Optional)



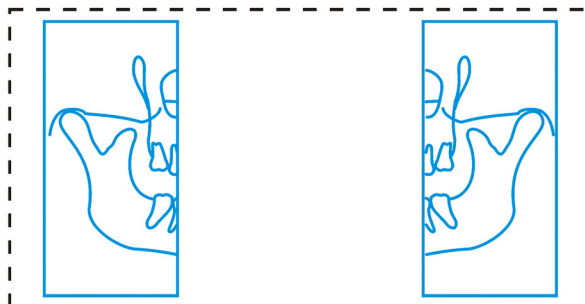
Adult panoramic or five freely selectable partial sections. Magnification 1.25



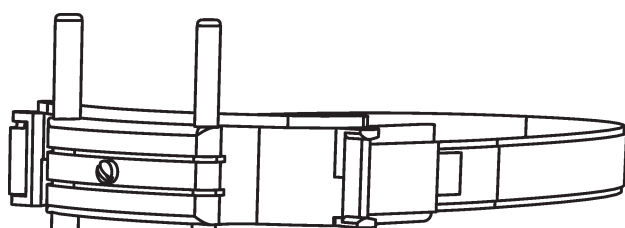
Reduced width and height panoramic (child) or five freely selectable partial sections. Magnification 1.25



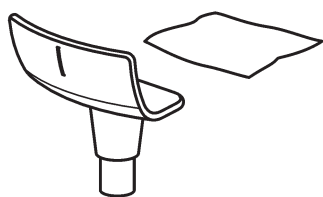
Temporomandibular joint. Magnification 1.25



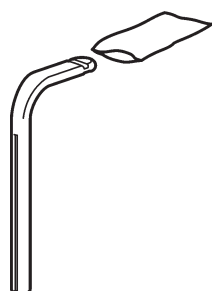
2.6 Positioning devices



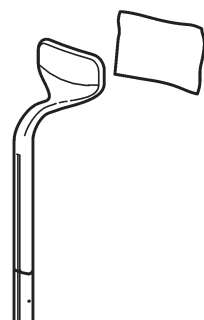
Forehead support



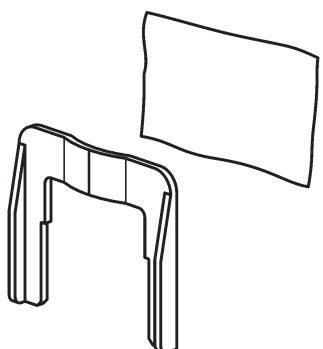
Chin cup
Disposable cover



Bite block
Disposable cover



Lip holder
Disposable cover



Lip support
Disposable cover

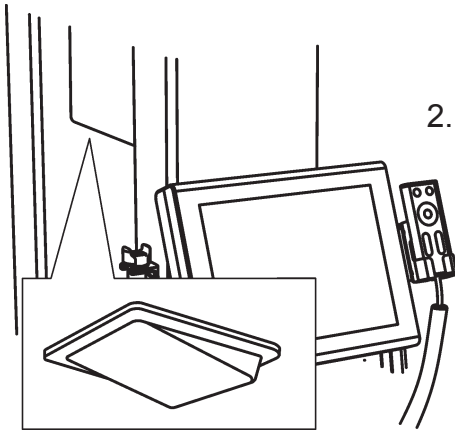
3. Taking an exposure

3.1 Preparing the system

1. **PC:** Switch the PC on.

IMPORTANT NOTE:

Make sure that the hardware key (dongle) is connected to the PC. If a hardware key has been removed the system will not work correctly. Note that some systems have two hardware keys.



2. Switch the unit on. The on/off switch is on the under side of the electronics cabinet.

A message will appear on the control panel asking you to press and hold the chair down button to complete unit start up.

CAUTION: Crushing Danger!

Before pressing the chair down button remove all objects, for example drawers, wheel chairs, stools etc., from around the chair to avoid damage to the unit or injury to people.



3. Press and hold the chair down key until the unit stops moving.
A message will then appear asking you to select a patient and then start image capture.

The system is now ready to take an exposure.

3.2 Taking a 3D exposure

1. **PC:** Open a new or existing patient or select a patient from the work list. Refer to the user's guide supplied with the SCANORA® Workstation software for information on how to do this.

NOTE:

The 3D viewing software must NOT be open when taking an exposure.

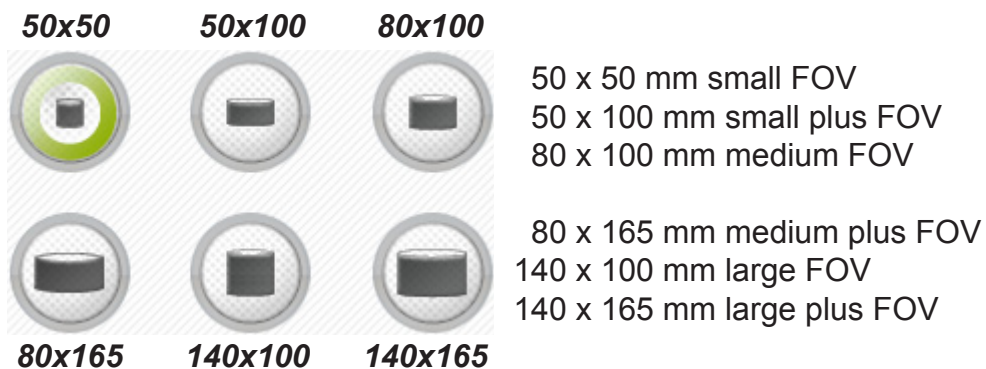


2. **PC:** Click the Image Capture button. The image capture window will open.

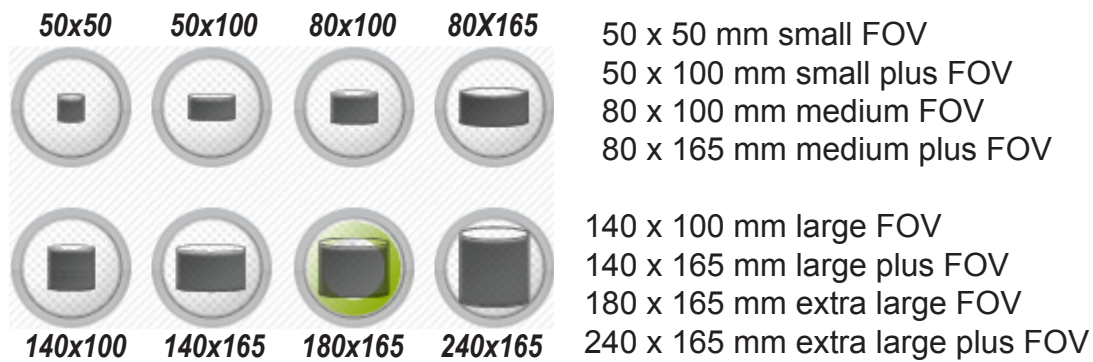


3. Touch the 3D button to select the 3D program mode.

4. Select the Field Of View (FOV):

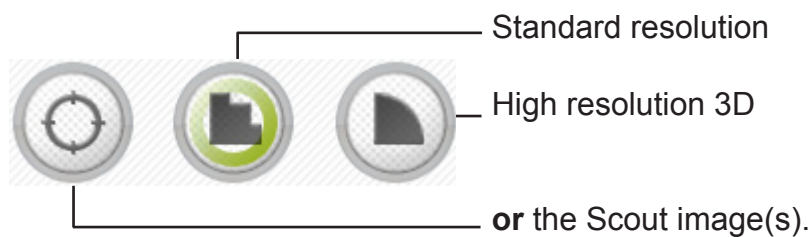


Unit with optional extra large FOVs

**NOTE:**

For the optional extra large FOVs the unit will take **two** large FOV images and then combine (stitch) them to form a single extra large FOV image.

5. Select the 3D image resolution:



Press the scout button repeatedly to scroll through the three scout image options, lateral (Lat), anterior-posterior (AP) or lateral plus anterior-posterior (Lat+AP). The option and size of the selected scout image will appear on the information window.

NOTE:

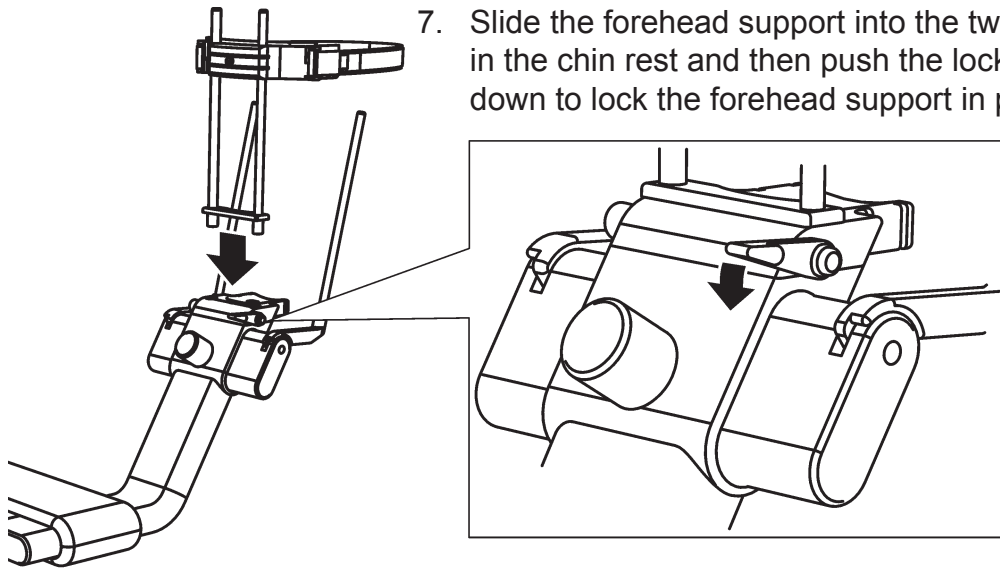
It is recommended that a scout image or images are taken before the 3D image is taken to ensure that the region of interest (ROI) you wish to examine is correctly positioned within the 3D field of view (FOV).



6. Select the mA.

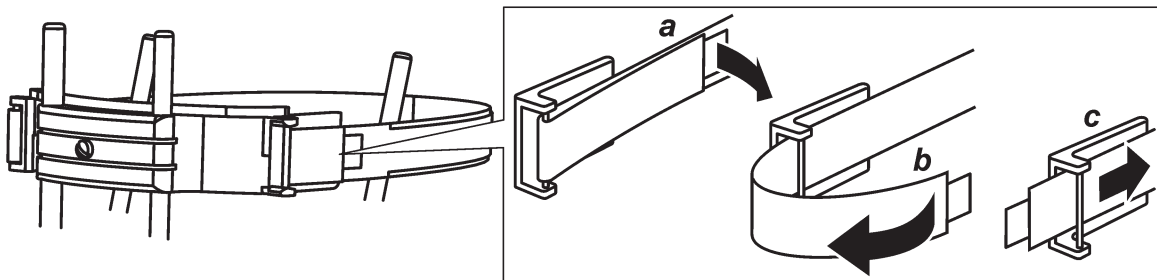
CAUTION:

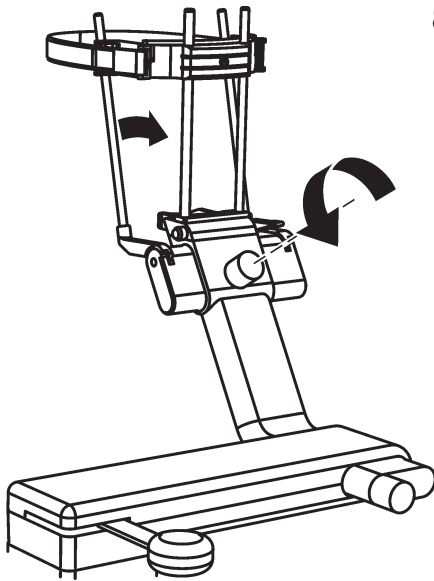
When taking an exposure of a child use the lowest possible mA that will allow you to take an image of sufficient quality for you to perform the required diagnostic examination.



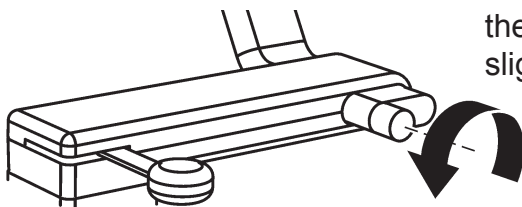
7. Slide the forehead support into the two holes in the chin rest and then push the locking lever down to lock the forehead support in position.

Release the head strap.

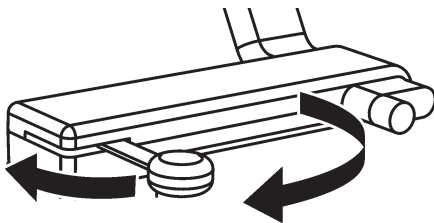




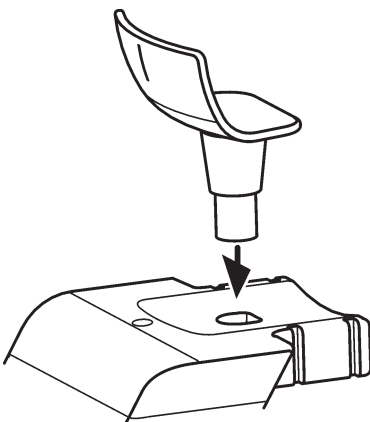
8. Rotate the temple supports knob to open the temple supports as far as they will go and then pull the temple supports away from the seat.



9. Rotate the head support adjusting knob to move the head support to its mid point. You will feel slight "click" when you reach this position.



10. Turn the head support lever to the left to release the head support and then rotate the head support away from the seat to the open position.



11. Insert the chin cup into the chin rest.
NOTE:
Use a new disposable cover for every patient.



12. Press the chair down key to drive the chair down so that it is low enough for the patient to enter unit.

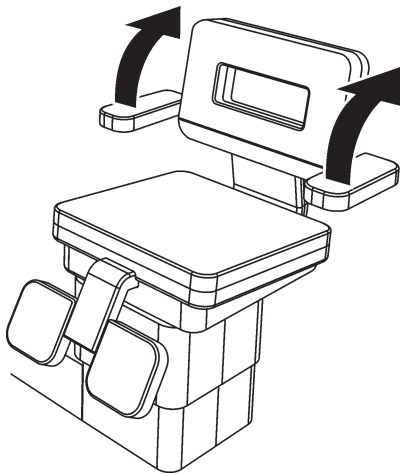
13. Ask the patient to remove any spectacles, dentures, jewellery and hair clips and pins. Place a protective lead apron around the patient's neck to protect the patient's thyroid gland from radiation.

NOTE:

If the patient is nervous or a child, you can demonstrate how the unit works to reassure them. Touch the **T** (Test) button and then press and hold the exposure button. The unit will complete an exposure cycle without generating x-rays.

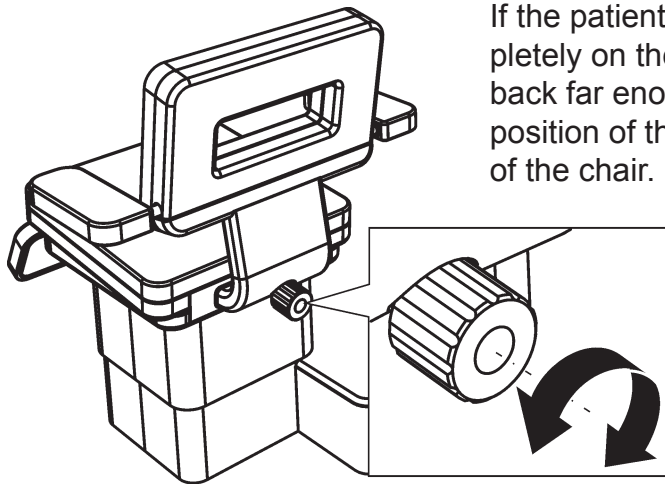


14. Press the key button to drive the rotating unit to the 3D ready position.



15. If necessary lift up the arm rests and then ask the patient to sit on the chair. Make sure that the patient is sitting straight and in the middle of the chair with their back pushed against the backrest. Also make sure that they are sitting in a position in which they feel comfortable.

With small patients and children you may have to use cushions to position the patient at the right height.



If the patient is very large and cannot sit completely on the seat or is small and cannot sit back far enough, adjust the forward/backward position of the backrest with the knob at the rear of the chair.



Wheelchair patients

Adjust the height of the unit chair so that the seat is level with the wheelchair seat or as near as possible at the same level.

Position the patient in the wheelchair as close as possible to the left-hand side of the unit chair with the patient facing forwards.

Ask the patient to put the wheelchair's brake on so that wheelchair cannot move.

Make sure that the left-hand arm rest of the unit chair is in the raised position.

Manually rotate the rotating unit so that the detector head is at the front. This will make it easier for the patient to enter the unit.

Ask the patient to remove or lower the armrest on the right-hand side of the wheelchair.

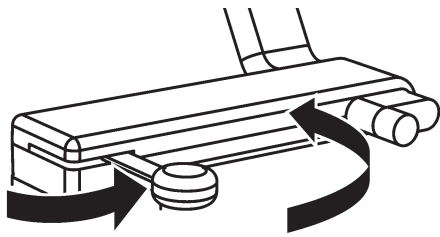
Ask the patient to slide from the wheelchair onto the unit chair.

When the patient is in the unit chair lower the left-hand chair armrest.

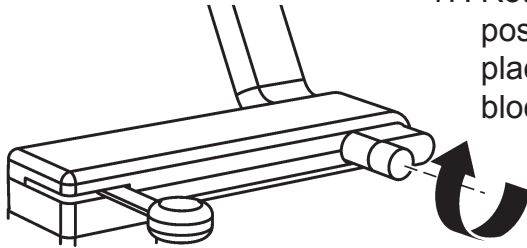
Remove the wheelchair from the unit environment.

NOTE:

After taking the exposure repeat the above procedure in the reverse order to get the patient back into the wheelchair.



16. Carefully rotate the head support towards the patient until it stops. Turn the head support locking lever to the right to lock the head support in position.



17. Rotate the head support positioning knob to position the head support so that the patient can place their chin on the chin cup or bite the bite block.

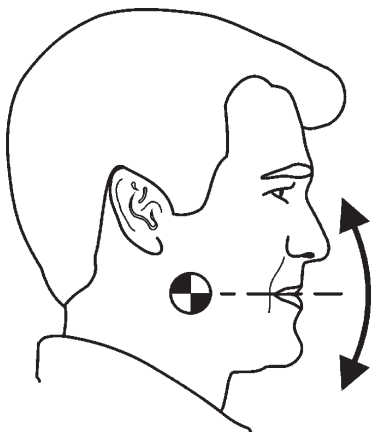


18. Press the light key to switch the patient positioning lights on.



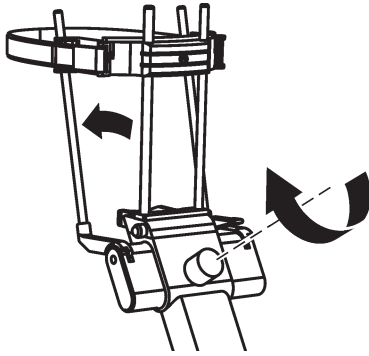
NOTE:

If the patient positioning lights do not come on the rotating unit is not in the 3D ready position. To switch the lights on, press the return key to drive the unit to the 3D ready position and then press the light key to switch the patient positioning lights on.



19. Press the head support up/down keys to level or adjust the angle of the patient's head.



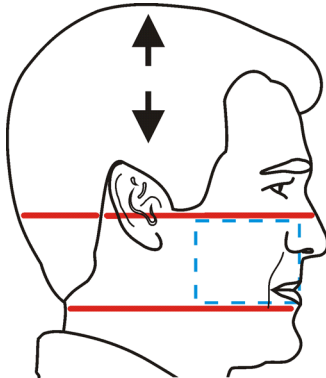


20. Push the temple supports towards the patient so that they are positioned on both sides of the patient's head. Carefully rotate the temple support knob to close the temple supports so that they grip the patient's head.

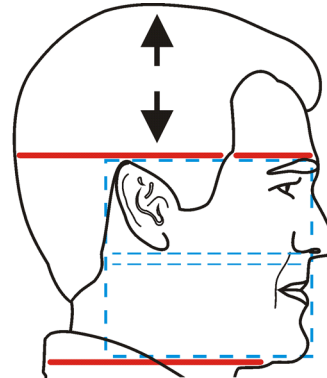


21. Press the seat height adjusting keys to position the ROI within FOV you have selected. The upper light beam indicates top of the FOV and the lower light beam the bottom of the FOV.

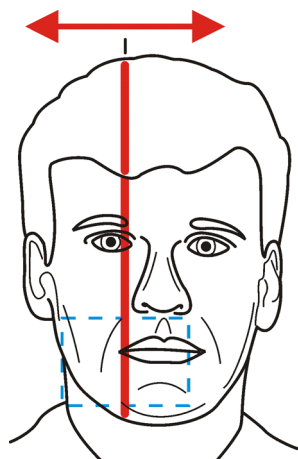
If you are taking an XL or XL+ FOV image position the lower light level with the bottom of the patient's chin. For an adult patient with average size head this will place the boundary between the two large FOV images in an area away from the crowns.



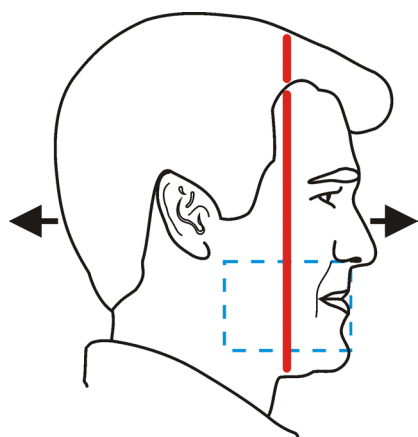
S, S+, M, M+, L, L+



XL, XL+



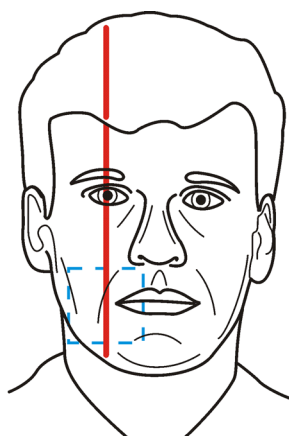
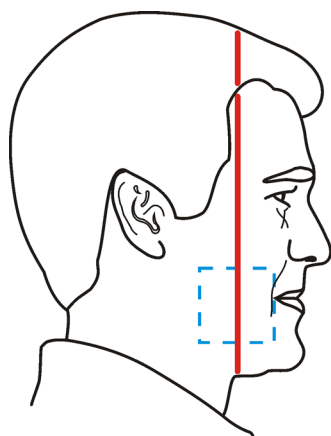
22. The sagittal light (vertical front light) indicates the center of the FOV in the sagittal direction. Press the left / right field of view positioning keys to position the sagittal light so that it is in the center of the ROI you wish to examine.

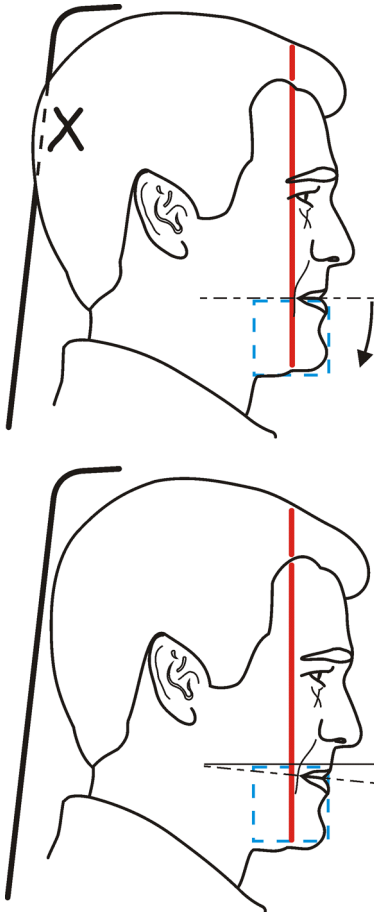


23. The lateral light (vertical side light) indicates the center of the FOV in the lateral direction. Press the forwards / backwards field of view positioning keys to position the patient so that the lateral light is in the center of the ROI you wish to examine.



If you are taking a scout view the sagittal light and the lateral light indicate the center of the scout view viewed from the front and from the right-hand side of the patient respectively.

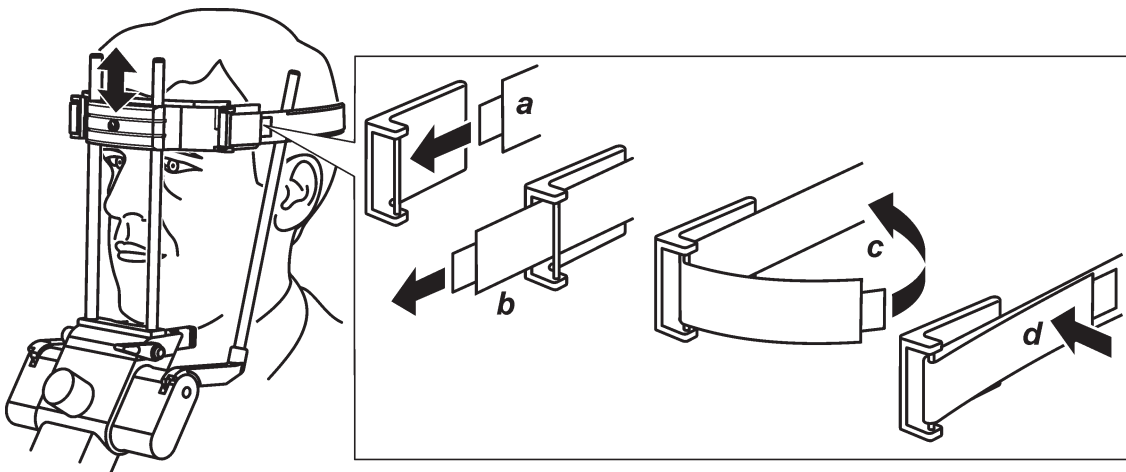


**CAUTION - Small FOV exposures:**

If you are going to take an exposure of the anterior tip of the chin using the small FOV the patient must be positioned as far back as possible. If you are NOT using the forehead support you may have to tilt the patient's head down slightly so that the sensor will not touch the back of the patient's head during the exposure.

It is recommended you that you take a test exposure to check whether or not the sensor will touch the patient's head and whether the patient's head will have to be tilted.

24. Slide forehead support up or down until it is positioned in front of the patient's forehead. Wrap the forehead support strap around the patient's head, slide the strap through the buckle and then gently pull the strap to tighten it around the patient's head. Fold the strap backwards and then secure it in position.



25. Tell the patient not to move for the duration of the exposure.

If you are taking an **XL or XL+** 3D image tell the patient that **TWO** images will be taken and that after the first image has been taken the chair will automatically descend and the unit will take a second exposure.



26. Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Make sure that you can see and hear the patient during the exposure.

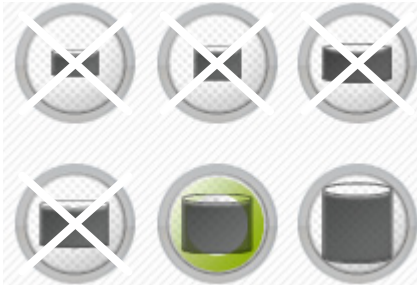
Press and hold down the exposure button for the duration of the exposure. The exposure starts when you hear the exposure warning signal and the exposure warning indicator appears on the control panel. The rotating unit will rotate around the patient's head and take the exposure. When the exposure warning signal and rotating unit stop, the exposure has been taken.



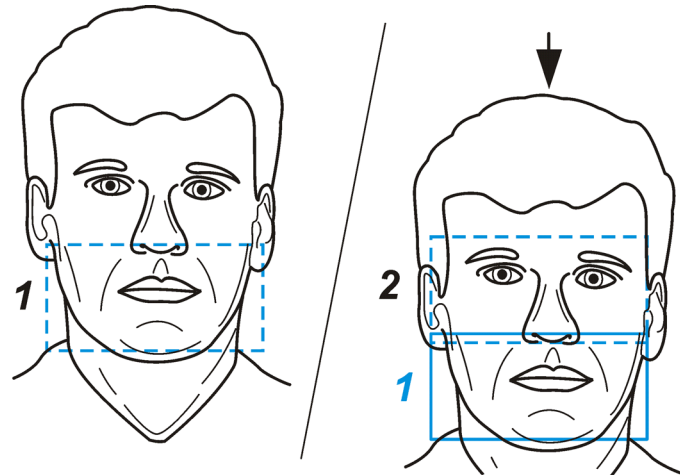
If you are taking a scout image or scout images the rotating unit will either take a single image from the side (lateral) or a single image from the rear (anterior-posterior) or two images, one from the side and one from the rear.

If you are taking a S, S+, M, M+, L or L+ 3D image the rotating unit will rotate around the patient's head once and then stop.





If you are taking an XL or XL+ 3D image the rotating unit will rotate around the patient's head, take the first half of the image (the bottom half) and then stop. The chair will then automatically descend and the rotating unit will then rotate around the patient's head in the opposite direction and take the second half of the image (the top half).



When the audible signal stops and the exposure warning symbol disappears from the touch control panel the exposure has been taken.

27. It will take 1 to 5 minutes to process and transfer the 3D image to the PC. After transfer, open the image window and double click the 3D image to open it.

IMPORTANT NOTE - XL and XL+ FOVs

If the patient moved between the first and second exposure or if the boundary between the two large FOV images is not clearly defined (e.g. too many metal artifacts), the software may not be able to properly combine the two images into a single XL or XL+ 3D image. If this is the case, two separate XL or XL+ 3D images will be produced.

If the boundary between the XL and XL+ 3D images is not clearly defined but the software **is able** to combine the two 3D images the dimensional accuracy across the boundary area may be reduced.

NOTE:

If you took a scout image it will take 10 - 20 seconds for the image or images, to appear on the unit control panel.



If the FOV is **NOT** positioned correctly, touch the OK key (on the image display), reposition the patient and take another scout image.



If the patient is positioned correctly, touch the OK key and then select the resolution you require and take the 3D image.



28. After the 3D image appears on the PC display press the **Return** key to drive the rotating unit to the ready position.



29. Drive the chair to its lowest position, open the head support and guide the patient out of the unit.

30. **PC:** The 3D image can be examined using the 3D imaging software.
Refer to the documentation supplied with the 3D imaging software.



31. **PC:** Click the **Abort Capture** button when you have taken all the required images,

or



Touch the **End study** button to finish the examination.

3.3 Taking a Panoramic exposure (Optional)

1. **PC:** Open a new or existing patient or select a patient from the work list. Refer to the SCANORA® Workstation software users guide for information on how to do this.



2. **PC:** Click the Image Capture button.



3. Touch the Panoramic button to select the Panoramic program mode. The button will change color.

4. Select the panoramic program you wish to use:



adult panoramic

child panoramic

temporomandibular joints (TMJ)

Partial adult or child panoramic exposure.

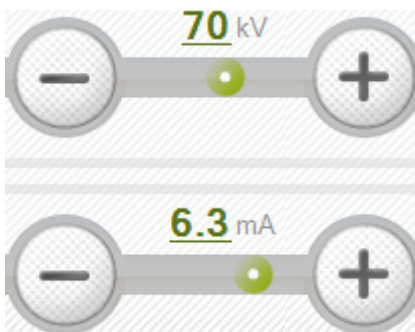


Touch the partial panoramic segments to disable those that you do not wish to expose, the segments will change color.

**NOTE:**

The images produced by selecting the rear two segments from the partial panoramic program are not the same as those produced by the dedicated TMJ program.

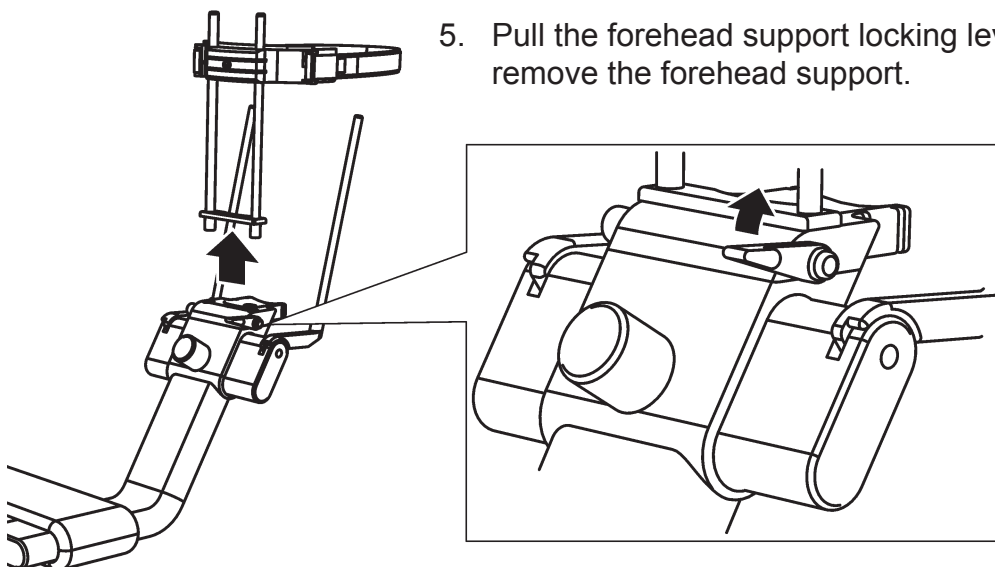
The TMJ program images have a different projection and are wider than the partial panoramic images.



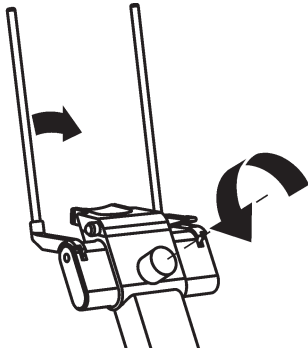
4. Select the kV and mA.

CAUTION:

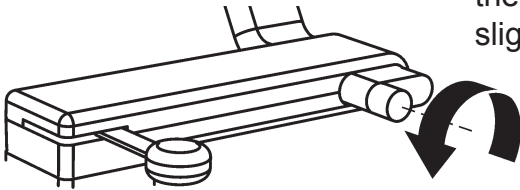
When taking an exposure of a child use the lowest possible kV (67kV recommended) and mA (4 - 5.3mA recommended) that will allow you to perform the required diagnostic task.



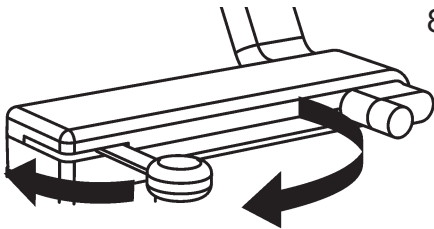
5. Pull the forehead support locking lever up and remove the forehead support.



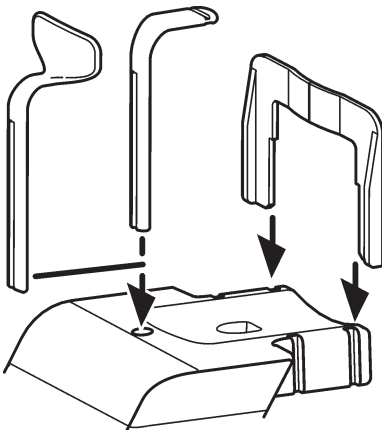
6. Rotate the temple supports knob to open the temple supports as far as they will go and then pull the temple supports away from the seat.



7. Rotate the head support adjusting knob to move the head support to its mid point. You will feel slight "click" when you reach this position.



8. Turn the head support locking lever to the left to release the head support and then rotate the head support away from the seat.



9. Insert the required positioning device, bite block, lip rest or lip support, into the head support. Place the appropriate disposable cover on positioning device.

NOTE:

Use a new disposable cover for every patient.



10. Press the seat height adjusting keys to drive the chair down so that it is low enough for the patient.

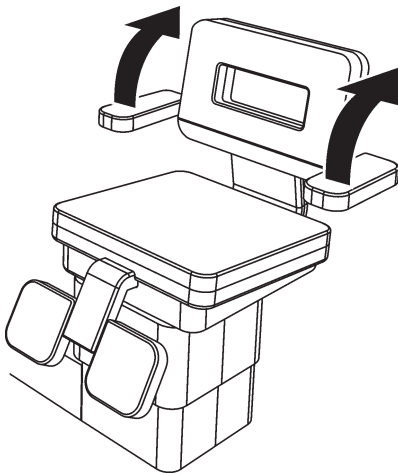
11. Ask the patient to remove any spectacles, dentures, jewellery and hair clips and pins. Place a protective lead apron around the patient's neck to protect the patient's thyroid gland from radiation.

NOTE:

If the patient is nervous or a child, you can demonstrate how the unit works to reassure them. Touch the **T** (Test) button and then press and hold the exposure button. The unit will complete an exposure cycle without generating x-rays.

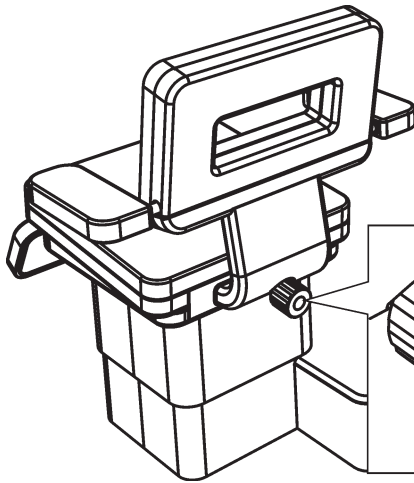


12. Press the Return button to drive the rotating unit to the ready position.

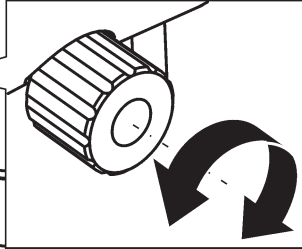


13. If necessary lift up the arm rests and then ask the patient to sit on the chair. Make sure that the patient is sitting straight and in the middle of the chair with their back pushed against the backrest. Also make sure that they are sitting in a position in which they feel comfortable.

With small patients and children use cushions to position the patient at the right height.



If the patient is very large and cannot sit completely on the seat or is small and cannot sit back far enough, adjust the forward/backward position of the backrest with the knob at the rear of the seat.



Wheelchair patients

Adjust the height of the unit chair so that the seat is level with the wheelchair seat or as near as possible at the same level.

Position the patient in the wheelchair as close as possible to the left-hand side of the unit chair with the patient facing forwards.

Ask the patient to put the wheelchair's brake on so that wheelchair cannot move.

Make sure that the left-hand arm rest of the unit chair is in the raised position.

Manually rotate the rotating unit so that the detector head is at the front. This will make it easier for the patient to enter the unit.

Ask the patient to remove or lower the armrest on the right-hand side of the wheelchair.

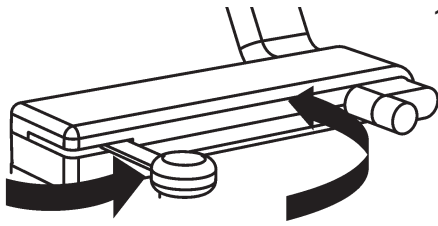
Ask the patient to slide from the wheelchair onto the unit chair.

When the patient is in the unit chair lower the left-hand chair armrest.

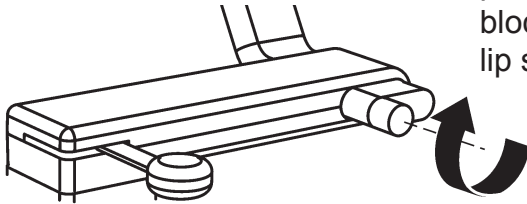
Remove the wheelchair from the unit environment.

NOTE:

After taking the exposure repeat the above procedure in the reverse order to get the patient back into the wheelchair.



14. Carefully rotate the head support towards the patient until it stops. Turn the head support locking lever to the right to lock the head support in position.



15. Rotate the head support positioning knob to position the head support so that the patient can place their chin on the chin rest and bite the bite block or press their lips against the lip holder or lip support.

If you are using the lip holder or lip support ask the patient to position their front teeth so that the front edges are touching.



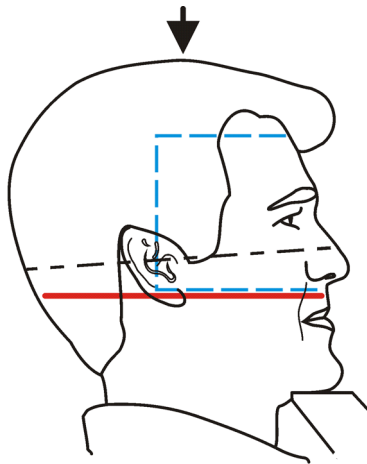
16. Press the light key to switch the patient positioning lights on.



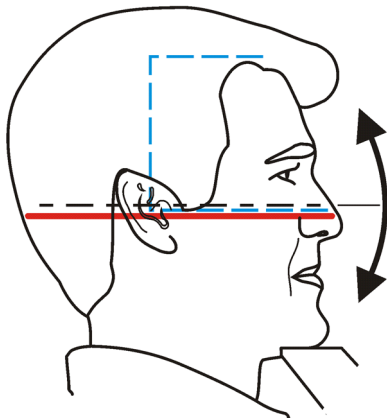
NOTE:

If the patient positioning lights do not come on the rotating unit is not in the panoramic ready position.

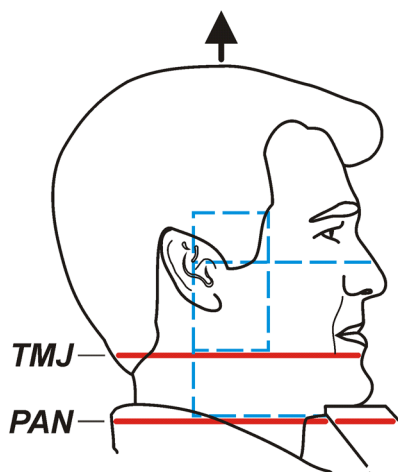
To switch the lights on, press the return key to drive the unit to the panoramic ready position and then press the light key to switch the patient positioning lights on again.



17. The horizontal light indicates the **bottom** of the panoramic and TMJ fields. However, the light can also be used to position the Frankfort plane. Press the down seat height adjusting key and position the patient so that the horizontal light is approximately level with the Frankfort plane.

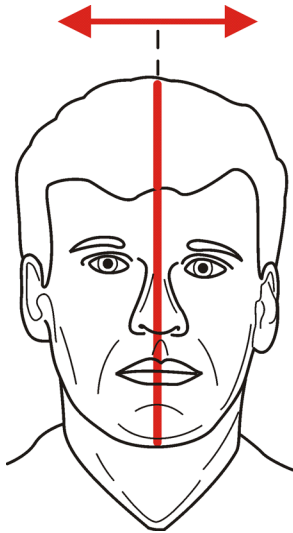


18. Press the head support up/down keys to adjust the tilt of the patient's head until the Frankfort plane is parallel to the horizontal light.



19. Now position the patient for the exposure you wish to take.
If you are taking a **panoramic (PAN)** exposure press the seat height adjusting keys and position the patient so that the horizontal light is under the patient's chin. If you are taking a **temporomandibular joint (TMJ)** exposure, position the patient so that the light is under the lower lip.

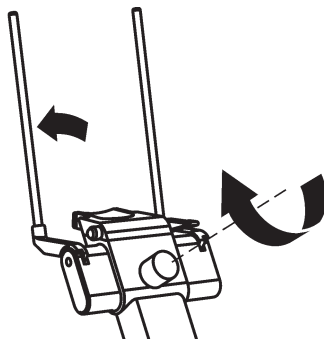
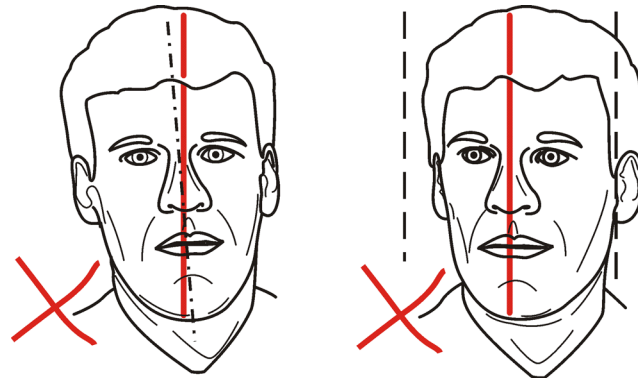




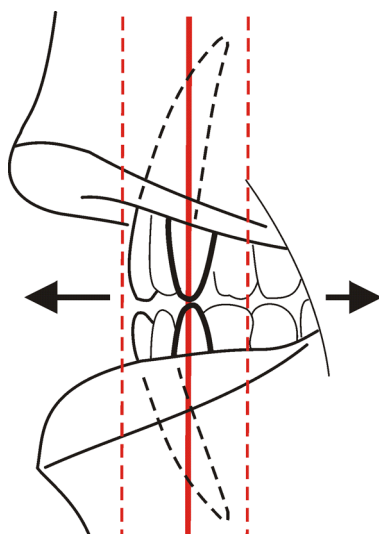
20. Check the position of the midsagittal light. If it is not on the midsagittal plane of the patient, press the left / right field of view positioning keys to position the light correctly.



Make sure that the patient's head is not turned or tilted to one side.



21. Push the temple supports towards the patient so that they are positioned on both sides of the patient's head. Carefully rotate the temple support knob to close the temple supports so that they grip the patients head.

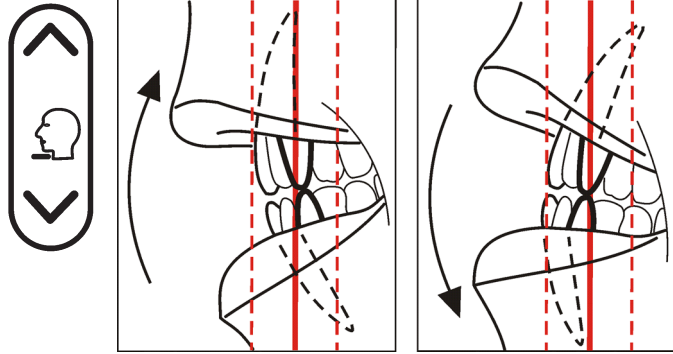
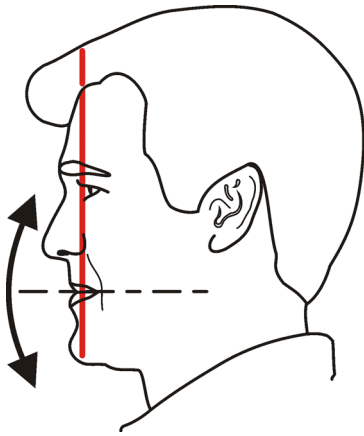


22. The focal trough light indicates the center of the focal trough which is approximately 10 mm wide at the front. Press the forwards / backwards positioning keys and position the focal trough light in the middle of the patient's upper canine.



This position is used for both **panoramic** and **temporomandibular joint** exposures.

23. If necessary readjust the tilt of the patient's head until the roots of the upper and lower front incisors are within the focal trough.



Note that you may have to reposition the focal trough slightly.

24. **IMPORTANT NOTE:**

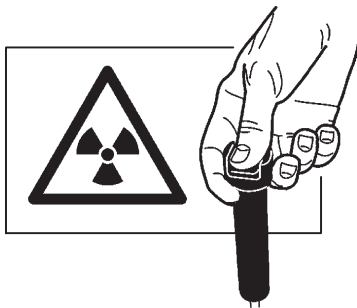
When you press the exposure button to take a panoramic exposure the panoramic sensor will automatically rotate to the exposure position. If, before taking an exposure, you want to check that the sensor will not touch the patient during the exposure sequence, press the **Return** key to drive the sensor to the exposure position and check its position in relation to the patient. For safety reasons, the height of the chair cannot be adjusted when the panoramic sensor is in the exposure position. If you wish to adjust the height of the chair you must press the **Return** key to drive the panoramic sensor back to the non exposure position.



25. Ask the patient to press their tongue against the roof of their mouth and remain still for the duration of the exposure, 15 seconds.

If you are taking a **temporomandibular joint** exposure ask the patient to open or close their mouth depending on which exposure you wish to take.

Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Make sure that you can see and hear the patient during the exposure.



26. Press and hold down the exposure button for the duration of the exposure.
The exposure starts when you hear the exposure warning signal and the exposure warning indicator appears on the control panel. The rotating unit will rotate around the patient's head and take the exposure. When the exposure warning signal and rotating unit stop, the exposure has been taken.



27. A preview image will appear on the unit control panel. Touch the OK key.



28. After the image appears on the PC display press the Return key to drive the rotating unit to the ready position.



29. Drive the chair to its lowest position, open the head support and guide the patient out of the unit.

30. **PC:** The panoramic image can be examined using the SCANORA® workstation software. Refer to the SCANORA® workstation software user's manual.



31. **PC:** Click the Abort Capture button when you have taken all the necessary images.

or



Touch the End study button to finish the examination.

3.4 After use

When the unit is not being used rotate the head support to the closed position and lock it in position with the head support locking lever.

4. Messages and error codes

4.1 Messages

**Dental imaging program not open.
Open dental imaging program from PC.**

The SCANORA® Workstation software in the PC has not been opened. Open the program to clear the message.

NOTE:

If the unit is connected to the PC through a router, this message indicates that the router is working but the PC may not be working.

**No Ethernet link
Check Ethernet cable between unit and PC**

Either the Ethernet cable between the unit and the PC is not connected or the PC has not been switched on.

Reconnect the Ethernet cable or switch the PC on to clear the message.

The exposure button was released during imaging.

Check the image to see if it is sufficient for the diagnostic task. If not take another image.

Reconstruction of the 3D image failed.

See if the image can be retrieved using the Retrieve last image option. If not take another image.

NOTE:

This message will also appear if the hardware key (dongle) used for software protection has been removed from the PC's USB slot.

PC's driver failed.

Switch the system off and then on again. If the message reappears, call service for help.

Examination closed before preview image(s) could be shown

The exit button was pressed before the images could be processed. The preview image(s) can be retrieved from the imaging software.

PC's driver failed for unknown reason.

Switch the system off and then on again. If the message reappears, call service for help.

Movement of the rotating unit was blocked.

The movement of the rotating unit was interrupted during the exposure.

Determine and remove the reason for the interruption and then take another image.

Panoramic detector was moved from its correct position.

The panoramic detector was moved during an exposure. Check the image to see if it is sufficient for the diagnostic task. If not take another image.

4.2 Error codes

If an error code appears,

Error xx

switch the unit and PC off and then restart the unit and PC. If the error message reappears, call service for help.

5. System Settings

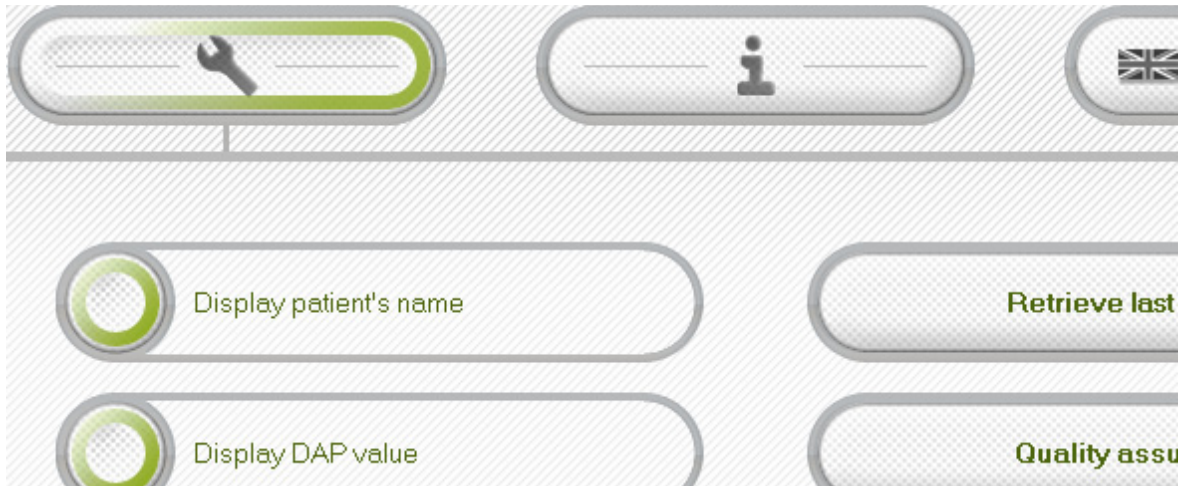
5.1 Unit Settings

Opening the Settings window



Touch the settings button at the bottom of the main window.

The settings window will appear.



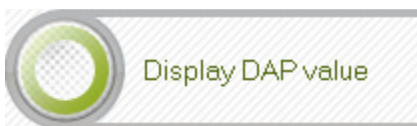
The Settings

Display patient's name



Allows you to select whether or not the name of the patient appears on the unit control panel.

Display DAP value



Allows you to select whether or not the DAP (Dose Area Product) appears on the unit control panel.

Retrieve last image

If the image is not transferred to the PC or there is a problem with the PC or the PC/unit connection, this function can be used to retrieve the last image from the unit memory.

CAUTION:

If the unit is switched off the last image taken will be lost.

WARNING:

Before retrieving the last image MAKE SURE that the patient, where the image must be stored, is open. If a different patient is open the retrieved image will be stored with this (the wrong) patient.

Quality assurance

See section 6. Quality assurance.

Information button

Displays the unit IP address and software versions.

Language button

Displays the GUI language options.

Touch the language button to select the language you require.

5.2 Software settings

Refer to the User's manuals supplied with the software.

6. Quality assurance

The quality assurance (QA) procedures for checking 3D and panoramic (optional) image quality must be carried out at regular intervals in accordance with local and national regulations related to the use of 3D and panoramic x-ray equipment.

Also follow local and national regulations concerning the evaluation of image quality of 3D and panoramic x-ray equipment. Also follow any regulations on how to take, examine, interpret and store test images.

Store the 3D and panoramic images produced during the QA procedures in a patient card opened specifically for QA images.

There are three steps in the 3D quality assurance procedure :

- Geometry calibration, checks the rotation geometry,
- Pixel calibration, checks the sensor and
- Quality check, checks the density values and also allows you to check the positioning lights.

All the QA steps must be carried out and they must be carried out in the order in which they are listed above

For the optional panoramic quality assurance a single image is used to check the image quality.

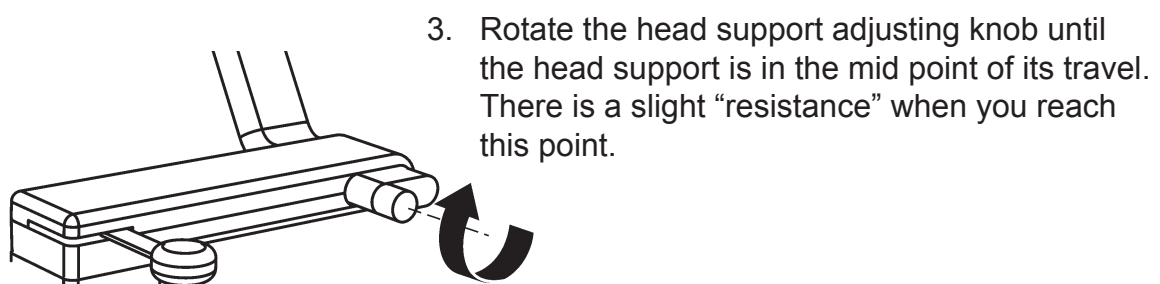
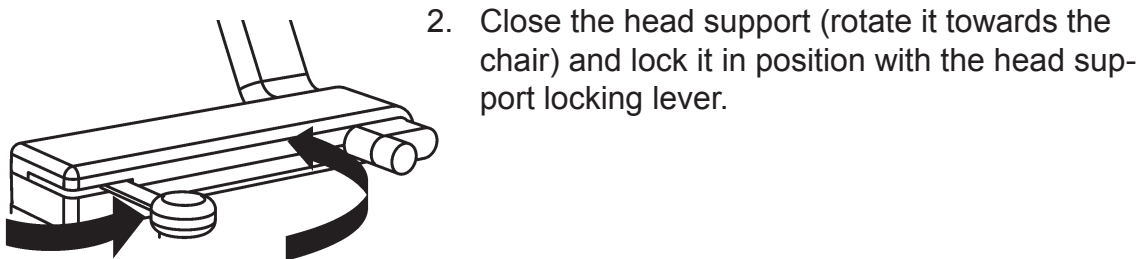
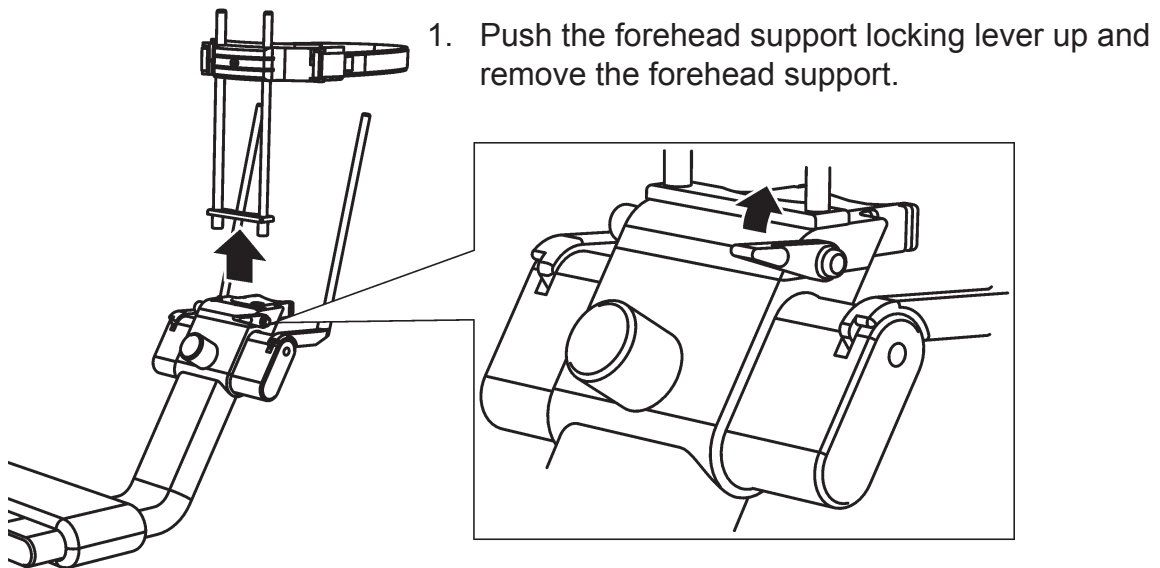
IMPORTANT NOTE

When the unit was installed a series of 3D and panoramic QA images were taken to verify image quality. These **original** QA images together with image parameters and viewing information are stored in a patient card opened specifically for these images.

The QA images taken during the following QA procedure can be compared with these **original** QA images to check image quality and monitor changes in image quality.

6.1 The 3D QA procedure

Starting the QA procedure.

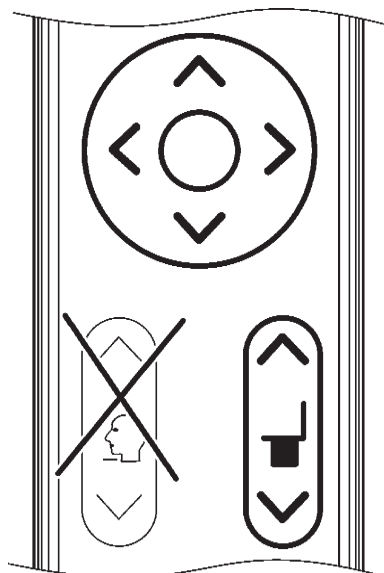
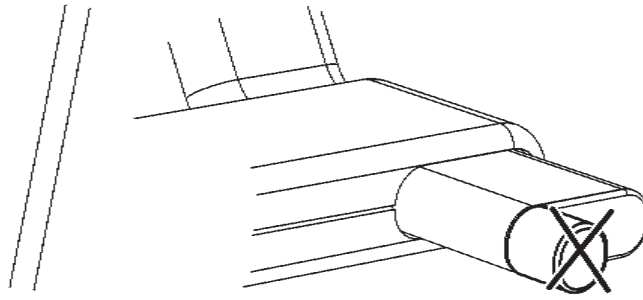
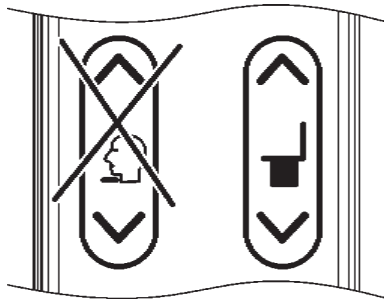


4. Restart the system as described in section 3.1 **Preparing the system.**

IMPORTANT NOTE:

When the system is ready the head support will be in the mid point of its vertical travel.

During the QA test procedure **DO NOT** use the head **support height adjusting keys** on the remote control nor the **head support adjusting knob** to adjust the position of the QA phantoms.



To adjust the position of the phantoms **ONLY** use the **Seat Height adjusting keys** and the **Field of View positioning keys** on the remote control to adjust the position of the QA phantoms.

5. **PC:** Open a patient card in which the QA images are, or can be, stored.

NOTE:

Do not open the 3D viewing software.

6. **PC:** Calibrate the contrast and brightness of the monitor to optimise its image quality. Refer to the SCANORA® Workstation software user manual for information on how to do this.



7. **PC:** Click the Image Capture button.

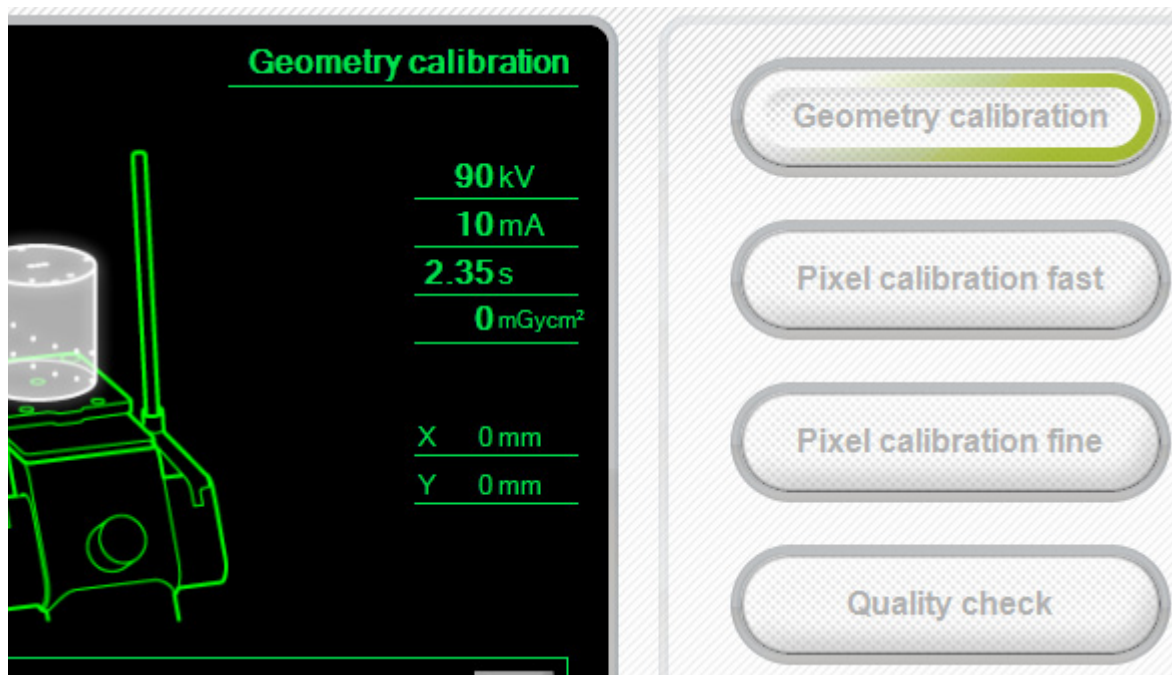


8. Touch the setting button at the bottom of the main window.
The settings window will appear.



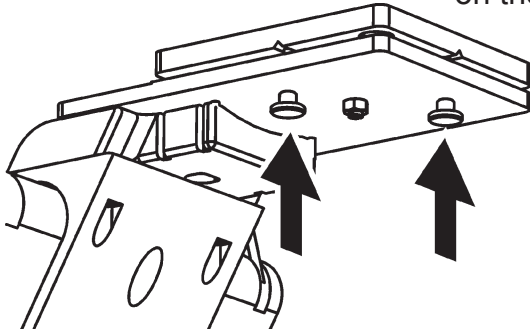
9. Touch the Quality assurance button.

The QA window will appear.

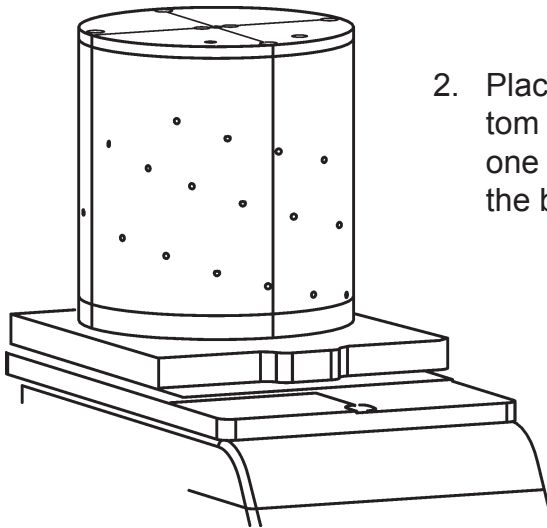


Geometry calibration

1. Place the adjustable phantom holder on the chin rest and then level the holder using the levelling screws on the under side. There is a spirit level on the holder.



2. Place the 3D phantom on the adjustable phantom holder. Note that it can only be placed in one position because of the different size pins in the base.

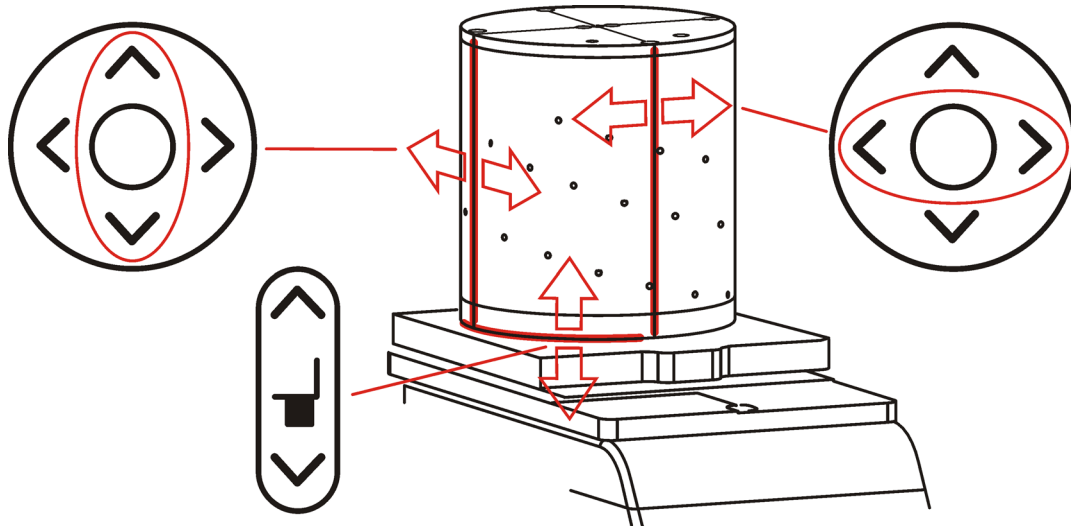


3. Press the Return key to drive the unit to the ready position.



4. Press the Lights key to switch the patient positioning lights on.

- 5 Use the seat height adjusting keys and the field of view positioning keys on the remote control to adjust the position of the 3D phantom. Position the phantom so that the vertical and horizontal lights coincide with the vertical and horizontal lines on the phantom and the horizontal light is at the bottom edge of the phantom.

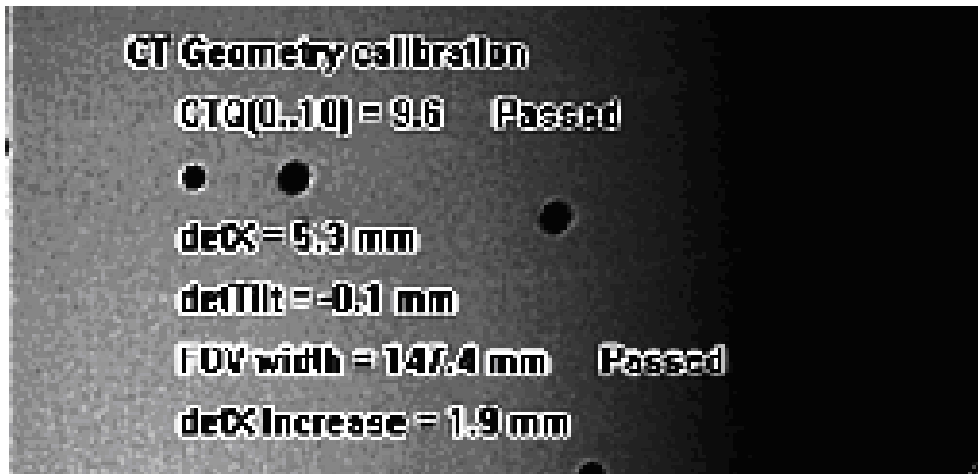


6. Touch the geometric calibration button to select the test.



7. Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Press and hold down the exposure button until the exposure is complete, this will take about 30 seconds.
8. After the exposure it will take approximately five minutes for the image to be reconstructed. When reconstruction is complete the image will appear briefly on the unit display and then the PC.

The word **PASSED** should appear on the image. This indicates that the unit has passed the geometry calibration test.



If the word **FAILED** appears on the image, the unit has failed the test.

If required compare the parameters of this image to those of the original QA image.

Recheck the position of the 3D phantom and reposition and relevel it if necessary. Repeat the test. If it fails a second time call service.



Touch the OK button to save the image and return to the QA window.

You must now carry out the pixel calibration test.

Pixel calibration fast

1. Remove the 3D phantom.

2. **CAUTION: Crushing Danger!**

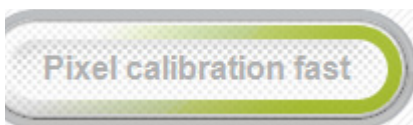
Before pressing the chair down button remove all objects, for example drawers, wheel chairs, stools etc., from around the chair to avoid damage to the unit or injury to people.



Press the seat height adjusting key to drive the chair down as far as it will go.



3. Press the Return key to drive the unit to the ready position.



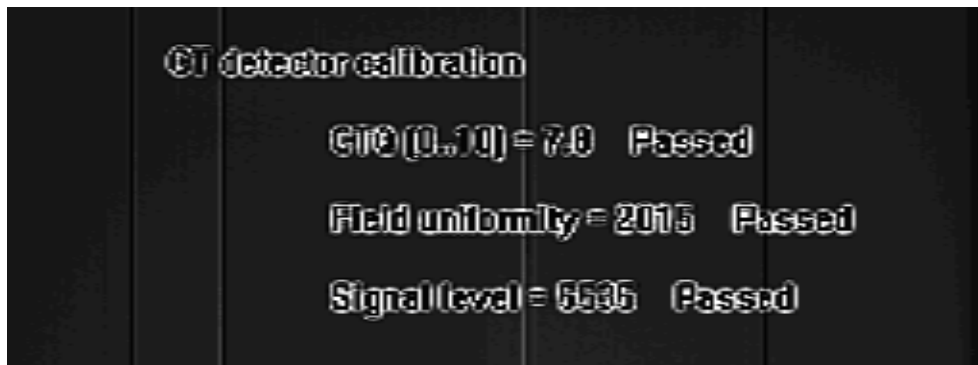
4. Touch the pixel calibration button to select the test.



5. Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Press and hold down the exposure button until the exposure is complete, this will take about 15 seconds.

6. After the exposure it will take approximately one and a half minutes for the image to be reconstructed. When reconstruction is complete the image will appear briefly on the unit display and then the PC.

The word **PASSED** should appear on the image. This indicates that the unit has passed the pixel calibration test.



If the word **FAILED** appears on the image, the unit has failed the test.

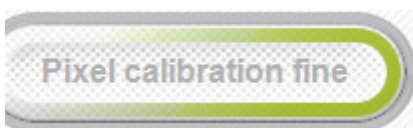
If required compare the parameters of this image to those of the original QA image. Repeat the test. If it fails a second time call service.



Touch the OK button to save the image and return to the QA window.

You must now carry out pixel calibration fine

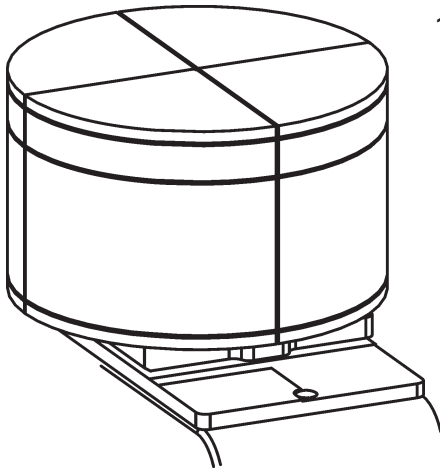
Pixel calibration fine



Carry out the pixel calibration fine in the same way as the pixel calibration fast.

You must now carry out the quality check.

Quality Check



1. Place the QC phantom on the adjustable phantom holder. Make sure that the pin in the base of the quality assurance phantom goes into the middle hole in the adjustable phantom holder.

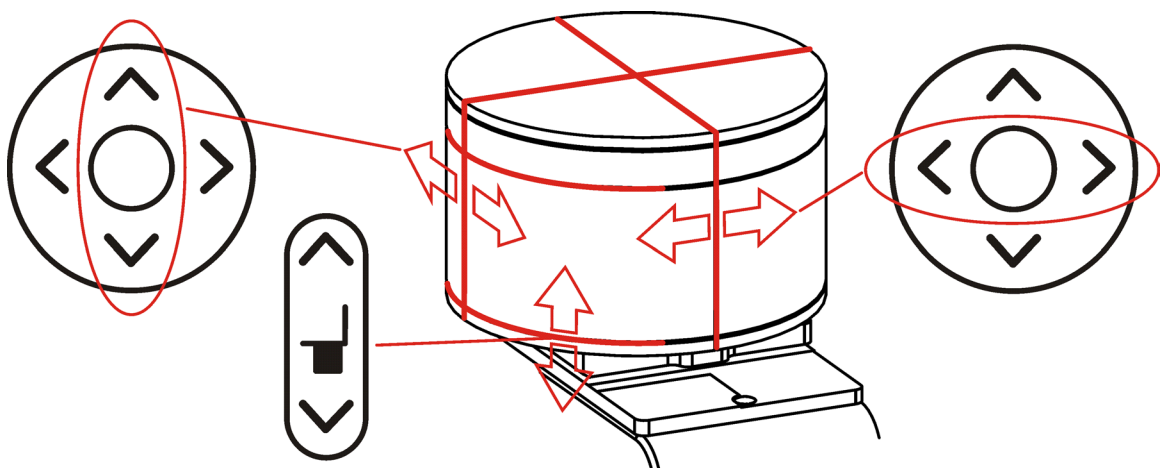


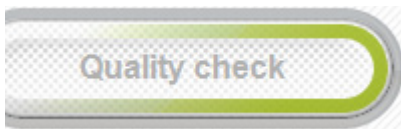
2. Press the Return key to drive the unit to the ready position.



3. Press the lights key to switch the patient positioning lights on.

4. As with the geometry calibration test, use the seat height adjusting keys and the field of view positioning keys on the remote control to adjust the position of the QC phantom. Position the patient positioning lights so that they coincide with the vertical and horizontal lines marked on the phantom.



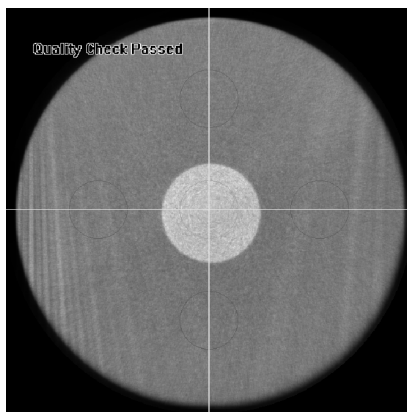


5. Touch the Quality Check button to select the test.



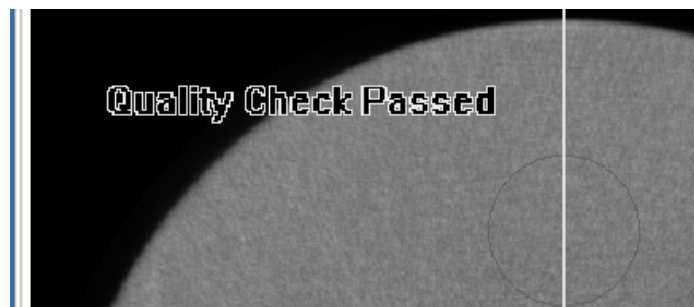
6. Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Press and hold down the exposure button until the exposure is complete, this will take about 15 seconds.

7. After the exposure it will take approximately three minutes for the image to be reconstructed. When reconstruction is complete the image will appear briefly on the unit display and then the PC.



8. **PC:** Open the 3D viewing software and then open the quality check image.

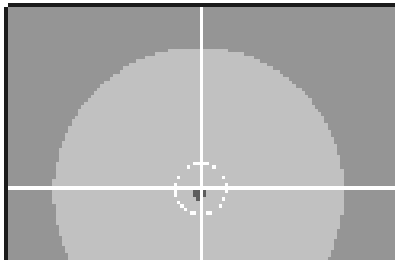
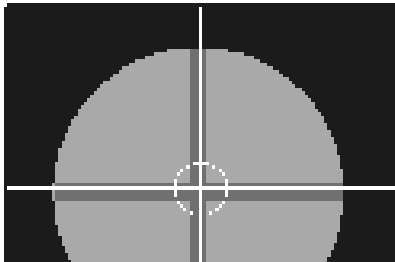
Scroll through the quality check image (the cylindrical 3D volume) until you see the word **PASSED**. This indicates that the unit has passed the Quality Check test.



If the word **FAILED** appears on the image, the unit has failed the test.
If required compare this image to the original QA image.
Recheck the position of the 3D phantom and reposition and relevel it if necessary.

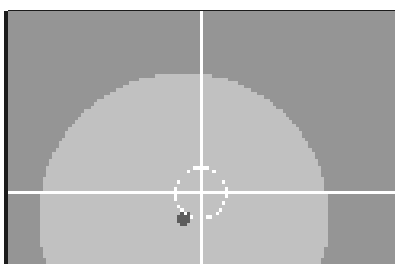
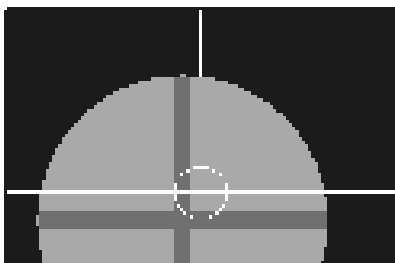
NOTE:

You can check if the QC phantom is level by scrolling through the volume (see step 9, next) and checking if the cross, at the top, and dot, at the bottom, appear within the white circles. If they do not, the QC phantom is not level. Repeat the test. If it fails a second time call service.



9. **PC:** Now check the position of the lights using the same image. Scroll to the top of the quality check image. A cross will appear. The center of the cross should be within the white circle at the center of the crosshairs. Now scroll to the bottom of the quality check image. In the center of the image you will see a dot. The dot should be within the white circle at the center of the crosshairs.

If both the center of the cross and the dot are within the white circle at the center of the crosshairs, the lights are correctly positioned.



If the center of the cross and the dot are not within the white circle, the lights are not positioned correctly and must be adjusted. Call service.



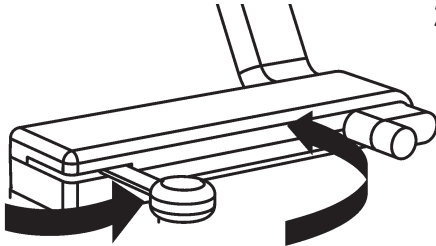
10. Touch the OK button to save the image and return to the QA window.



11. The QA test for 3D imaging is now complete. Touch the arrow button to exit the QA mode and return to the main program window.

6.2 The Panoramic QA procedure (OPTIONAL)

1. Start the system as described in section 3.1 **Preparing the system.**



2. Close the head support (rotate it towards the chair) and lock it in position with the head support locking lever.

3. **PC:** Open a patient card in which the QA images can be, or are, stored.

4. **PC:** Calibrate the contrast and brightness of the monitor to optimise its image quality. Refer to the SCANORA® Workstation software user manual for information on how to do this.



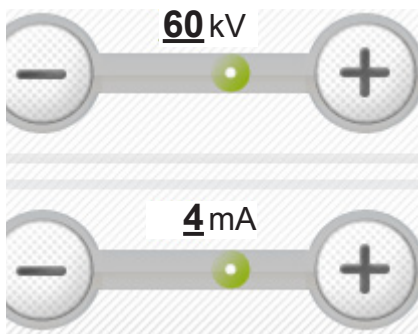
5. **PC:** Click the Image Capture button.



6. Touch the Panoramic button to select the Panoramic program mode.

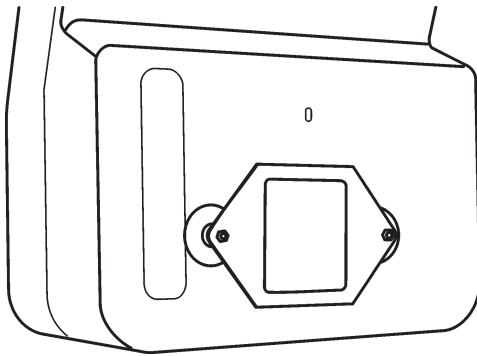


7. Select the adult panoramic program.



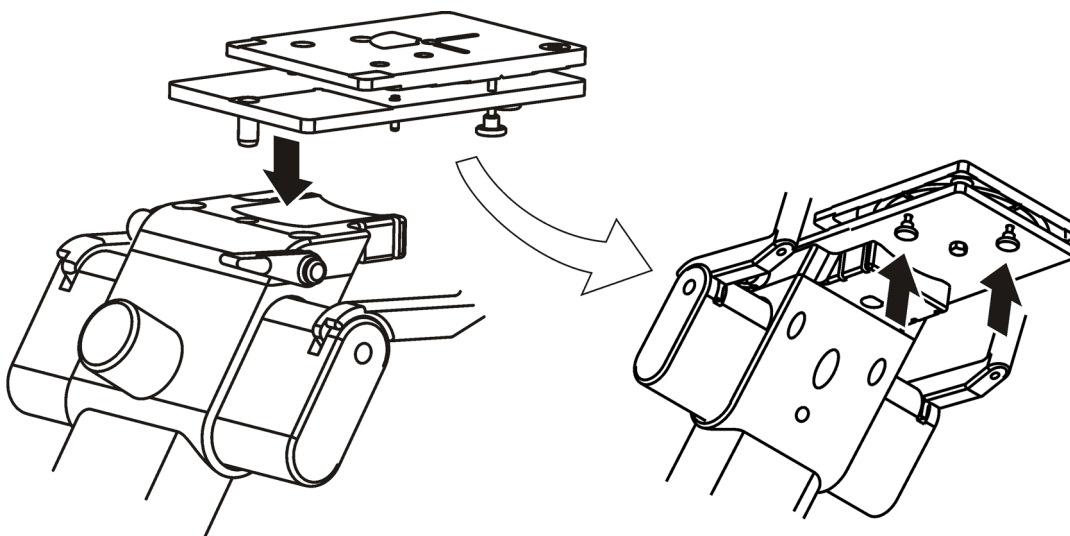
8. Select exposure factors 60 kV and 4 mA.

9. Push the temple supports towards the chair so that the panoramic sensor will not hit them during the exposure.

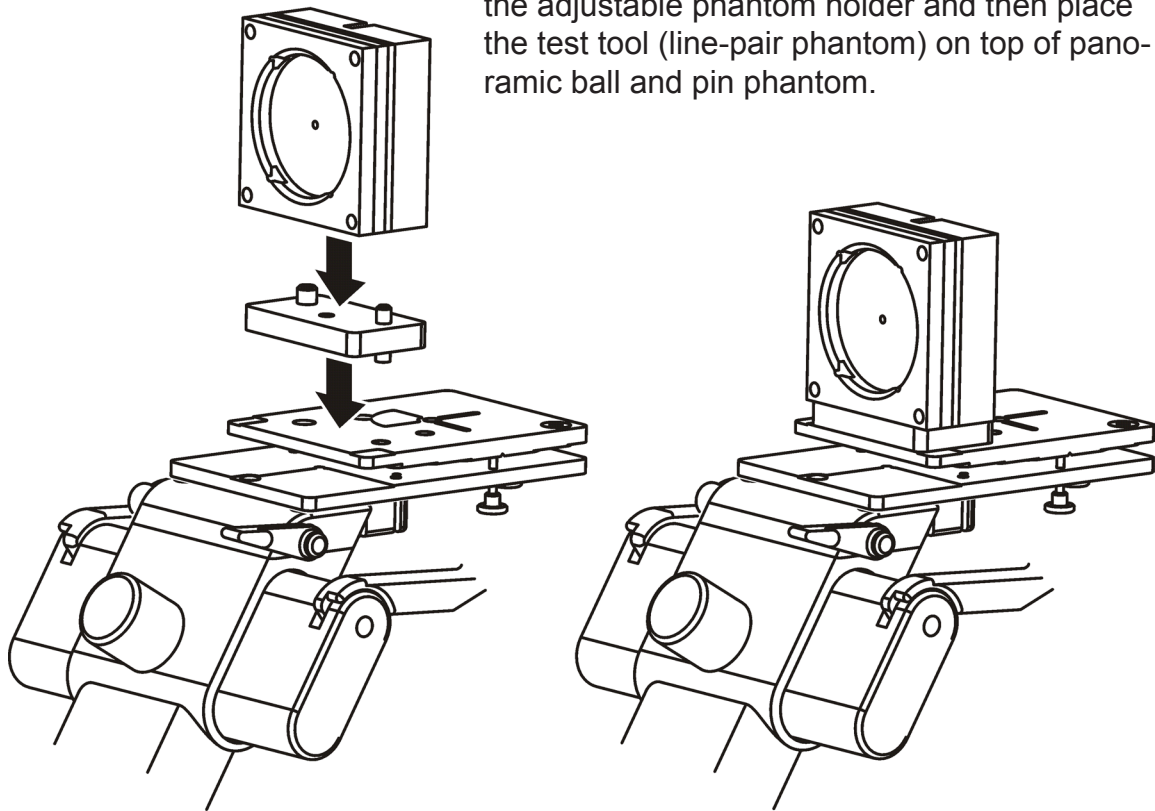


10. Attach the copper filter to the front of the tube-head assembly (in front of the collimator).

11. Place the adjustable phantom holder on the chin rest and then level the holder using the levelling screws on the under side. There is a spirit level on top of the holder.



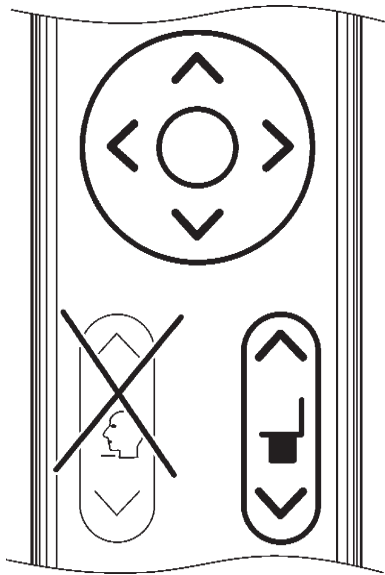
12. Place the panoramic ball and pin phantom on to the adjustable phantom holder and then place the test tool (line-pair phantom) on top of panoramic ball and pin phantom.



13. Press the Return key to drive the unit to the ready position.

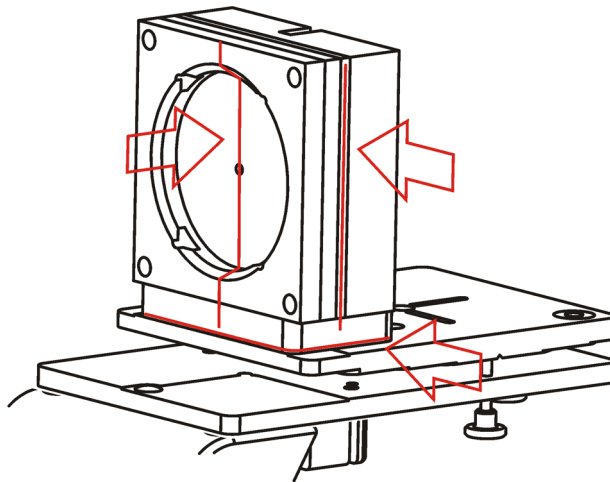


14. Press the lights key to switch the patient positioning lights on.



15. Use the **Field of View positioning keys** on the remote control to position the test tool so that the focal trough light strikes the middle of the clear plastic layer sandwiched between the two aluminium layers.

Use the **Seat height adjusting keys** ONLY to position the horizontal light so that it strikes the lower edge of the ball and pin phantom.



The midsagittal light beam should strike the middle of the test tool (the x axis position displayed on the control panel should be 0).

NOTE:

If the midsagittal light beam does not strike the middle of the test tool, carry out the 3D geometric calibration procedure to realign the unit.

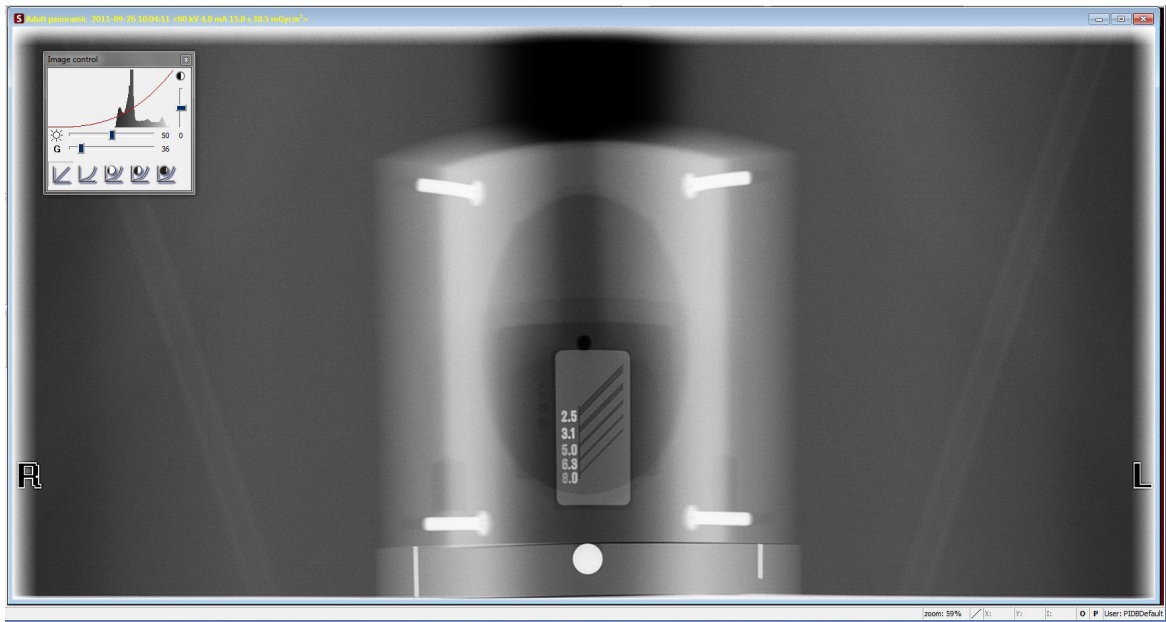


16. Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Press and hold down the exposure button. The exposure will last about 15 seconds.

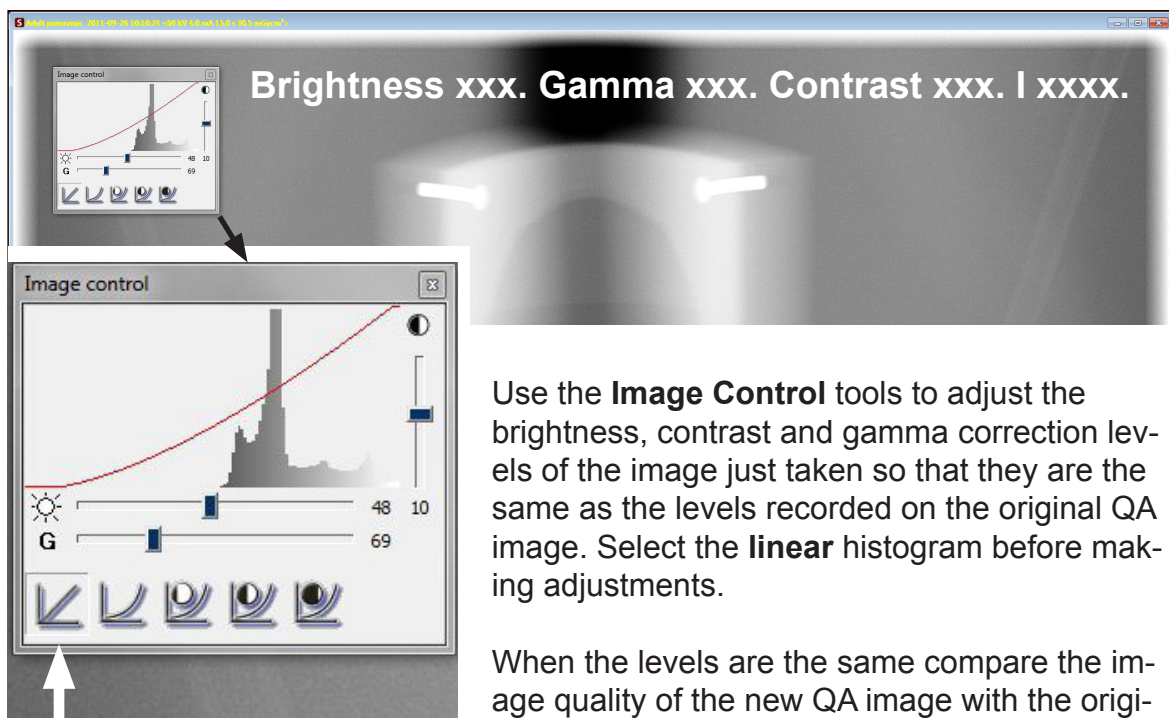


17. **PC:** Click the Abort Capture button.

An image of the test tool and the panoramic ball pin phantom will appear on the unit display and then the PC.

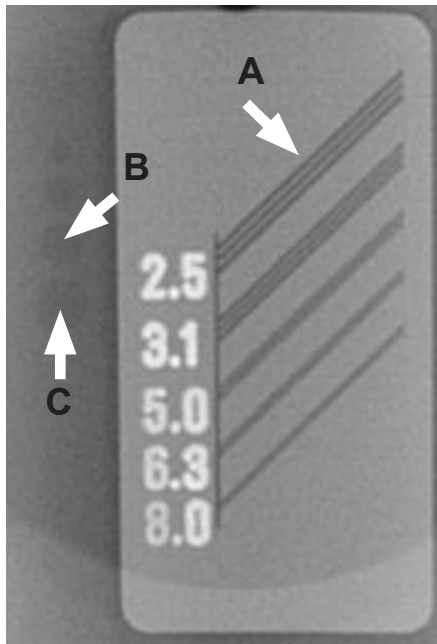


18. Open the original QA image that was taken when the unit was installed.



Use the **Image Control** tools to adjust the brightness, contrast and gamma correction levels of the image just taken so that they are the same as the levels recorded on the original QA image. Select the **linear** histogram before making adjustments.

When the levels are the same compare the image quality of the new QA image with the original QA image taken during installation.



The new QA image must meet the following requirements:

Minimum high contrast requirement (A)

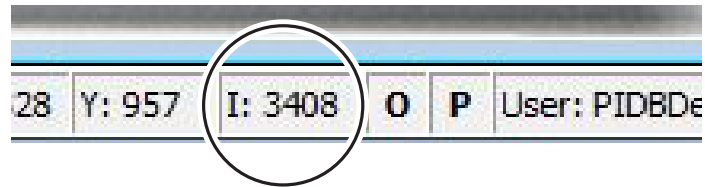
- 2.5 LP/mm (all 3 lines must be visible)

Minimum low contrast requirement (B)

- 2 holes minimum must be visible.

Grayscale value (C)

Position the cursor on the largest hole and then read the I (Original pixel) value (bottom right-hand corner of the display). Now compare it to the same value recorded on the original QA image taken during installation. The value should be the same, $\pm 20\%$.



Ball pin phantom dimensions

Use the measuring tools to check the new QA image and compare it to the original QA image. The ball in the center must be round and the distances from the right-hand pin and the left-hand pin to the ball must be the same within $\pm 0.5\text{mm}$.



Unexposed edge around the image

Without using the magnification tool you must be able to see an unexposed (white) border around the image

Homogeneity of the image

The whole image should be homogenous and artifact-free, no lines, bands or speckling.

PASS

If the quality of new QA image matches the quality of the original QA image, the unit has passed the panoramic image quality check.

FAIL

If the quality of the new QA image does not match the quality of the original QA image, the unit has failed the test.

Repeat the test. If it fails a second time call service.



19. Save the new QA image in the patient card specifically opened for it and then touch the Exit button to exit the test.

7. Care, maintenance and disposal

7.1 Cleaning and disinfecting the unit

Warning

Switch the unit off before cleaning it.
If you use a spray cleaner do not spray into any ventilation grills.

Unit surfaces and upholstery

All surfaces can be wiped clean with a soft cloth dampened with a mild detergent. DO NOT use abrasive cleaning agents or polishes on this equipment.

Positioning light covers

The positioning light covers are made of clear plastic. Use a soft cloth dampened with a mild detergent. NEVER use abrasive cleaning agents or polishes to clean the covers.

Surfaces that the patient touches

All surfaces and parts that the patient touches or comes into contact with must be disinfected after each patient. Use a disinfectant that is formulated specifically for disinfecting dental equipment and use the disinfectant in accordance with the instructions supplied with the disinfectant.

7.2 Checking that the unit operates correctly

General observations

If any of the unit's controls, displays or functions fail to operate or do not operate in the way described in this manual, switch the unit off, wait 30 seconds and then switch the unit on again. If the unit still does not operate correctly contact your authorized service technician for help.

If you hear the exposure warning tone but the exposure warning light on the display does not come on when an exposure is taken, stop using the unit and contact your authorized service technician for help.

If you do not hear the exposure warning tone when an exposure is taken, stop using the unit and contact your authorized service technician for help.

Quality assurance check

The quality assurance (QA) check must be carried out at regular intervals to check the image quality. See section 6.

Emergency stop knob

When the emergency stop button has been pressed down make sure that the unit movements do not operate.

Yearly maintenance

Once a year an authorized service technician must carry out a full inspection of the unit. During the inspection the following tests will be carried out:

- a kV/mA test
- a check that the safety ground is connected
- a check that the positioning lights operate
- a check that oil is not leaking from the tube head
- a check that all covers and mechanical parts are correctly secured and have not come loose.

A full description of all the tests and checks is described in the Service Manual.

7.3 Disposal

At the end of useful service life of the device, its spare parts, its replacement parts and its accessories make sure that you follow all local, national and international regulations regarding the correct and safe disposal and/or recycling of the device, its spare parts, its replacement parts and its accessories.

The device, its spare parts, its replacement parts and its accessories may include parts that are made of or include materials that are non-environmentally friendly or hazardous. These parts must be disposed of in accordance with all local, national and international regulations regarding the disposal of non-environmentally friendly or hazardous materials.

Hazardous materials and parts that are made of or contain these materials:

LEAD

Tubehead housing, collimator, circuit boards.

TUBEHEAD OIL

Inside tubehead

CESIUM IODIDE (CsI)

Amorphous silicon sensor, CCD sensor

7.4 Symbols that appear on the unit



Radiation warning



Dangerous voltage



On or enabled



Off or disabled



Connector for remote control



Exposure switch



Connector for Ethernet RJ45



Connector for exposure switch



Connector for external exposure light



Attention, consult accompanying documents

**CLASS 1 LASER PRODUCT****EN 60 825-1/A2:2001**Laser class label
(Patient positioning lights)

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.



Type B equipment

8. Warnings and precautions

8.1 To be observed during use

- The unit must only be used to take x-ray images of the dento-maxillo-facial complex and the head and neck areas, including the ear nose and throat (ENT) areas of the human skull. The unit must NOT be used to take any other x-ray exposures.
It is not safe to use the unit to take an x-ray exposure that the unit is not designed to take.
- Only professionally qualified dental and/or medical personnel are allowed to operate the unit and carry out any diagnoses based on output from the unit.
- The unit may be dangerous to the user and the patient, if the safety regulations in this manual are ignored, if the unit is not used in the way described in this manual and/or if the user does not know how to use the unit.
- This unit complies with the EMC (Electromagnetic Compatibility) according to IEC 60601-1-2. Radio transmitting equipment, cellular phones etc. shall not be used in close proximity of the unit as they could influence the performance of the unit.
- Because the x-ray limitations and safety regulations change from time to time, it is the responsibility of the user to make sure that all the valid safety regulations are fulfilled.
- It is the responsibility of the doctor to decide if the x-ray exposure is necessary.
- The minimum height of patient that can be x-rayed, without the optional cushion, is 140 cm (4 ft 7in) and the maximum is 205 cm (6 ft 9 in). These heights only apply to patients with normal anatomy.

- The unit chair can support a patient with a maximum weight of 150 kg.
- When taking an x-ray exposure of a patient with exceptional anatomy (typically very tall or large) use the test program (no x-rays) first to make sure that patient can be positioned correctly in the unit.
- Always use the lowest suitable x-ray dose to obtain the desired level of image quality.
- Avoid taking x-ray exposures of pregnant women.
- When taking an x-ray exposure of a child always use the lowest possible x-ray dose, the smallest possible image area and the lowest possible resolution that will allow you to perform the required diagnostic task.
- If the patient is using a pacemaker, consult the manufacturer of the pacemaker to confirm that the x-ray unit will not interfere with the operation of the pacemaker before taking an exposure.
- Always use disposable protective covers with the chin supports, chin rests and bite pieces.
- Disinfect all the surfaces that the patient is in contact with after every patient.
- Crushing Danger! The up/down chair movement is only safe if the area around the chair is clear of foreign objects that could become trapped under the edges of the chair. Before using the unit remove all foreign objects, for example drawers, wheel chairs, stools etc., from around the chair to avoid damage to the unit or injury to people.

- If the patient moves during the exposure and/or the imaging procedure is incorrect or incorrectly set up for the required examination and/or the unit is not correctly maintained, the accuracy of and measurement taken from the resulting images will be compromised.
- The user must protect himself/herself from x-ray radiation when taking exposures by standing behind a suitable x-ray radiation shield.
- The user must be able to see and hear the patient during an exposure.
- The user must see the radiation warning light and/or hear the audio warning signal during the exposure. If the unit is installed in such a place where the warning light cannot be seen, a separate warning light should be used. Please contact the local service for help.
- If the unit does not appear to be working correctly, switch the unit off and release the patient. Make sure that the unit operates correctly before you continue using it. If you are not sure whether the unit is operating correctly, please contact the local service.
- If the unit will not be used for a long time, switch the unit off and lock the exposure switch, in order to prevent unauthorized people using the unit.
- The annual maintenance as described in this manual is mandatory for the correct and safe operation of the unit.

8.2 General warnings

- There should be at least 10 cm clear space around the installation place of the unit.
- The place where the unit is to be installed and the position from where the user will take exposures must be correctly shielded from the radiation that is generated when the unit is operated.
- The unit or its parts must not be changed or modified in any way without approval and instructions from Soredex.
- To maintain low EMC emissions that conform with the MDD it is mandatory to use a shielded CAT6 Ethernet cable between the unit and the network.
- If this device will be used with 3rd party imaging application software not supplied by SOREDEX, the 3rd party imaging application software must comply with all local laws on patient information software. This includes the Medical Device Directive 93/42/EEC and/or relevant legal requirements in the USA.
- Do not connect any equipment to the unit that has not been supplied with the unit or that is not recommended by SOREDEX.
The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.
- The aperture plate and tubehead housing are made of lead (Pb), which is a toxic material. Do not touch these parts with your bare hands

Appendix A. Technical Data

A.1 Technical specifications

Type

SBR3D-2

Classification

IEC 60601-1: 1988 and A1+A2

IEC 60601-1-4: 1996 and A1

IEC 60601-2-7: 1998

IEC 60601-2-28: 1993

IEC 60601-2-32: 1994

IEC 60601-2-44: 2001 and A1

IEC 60601-1-3: 1994

IEC/EN 60601-1-2: 2001 and A1

UL 60601-1: 2003

CAN/CSA –C22.2 No. 601-1-M90 and S1+A2 standards

Complies with DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture

Performance Standards and European Union Directive 93/42/EEC (Medical Devices Directive).

EMC Class B+12

Safety according to IEC 60601-1

Protection against electric shock - Class I

Degree of protection - Type B applied with no conductive connection to the patient

Protection against the ingress of liquids - IP20

Disinfection methods:

- mild soapy water (non-abrasive)
- non-alcohol based disinfectant for the chin rest
- disposable plastic covers for bite piece, chin rest and lip support

For use in environments where no flammable anaesthetics nor flammable cleaning agents are present

Mode of operation - continuous operation/intermittent loading

Unit description

A dental cone beam 3D x-ray unit that generates 3D images and Panoramic (Optional) images.

The image receptors are an amorphous silicon flat panel sensor for cone beam 3D images and an (Optional) CCD sensor for panoramic images.

X-ray generator**TUBE**

Fixed anode

FOCAL SPOT

0.5 mm

TARGET ANGLE

15°

TARGET MATERIAL

Tungsten

OPERATING TUBE POTENTIAL3D imaging 90 kV (± 5 kV)Panoramic (Optional) imaging 60 - 81 kV (± 5 kV)**OPERATING TUBE CURRENT (AVERAGE)**3D imaging 0.9 - 2.3 mA (± 0.5)Panoramic (Optional) imaging 4 - 8 mA (± 1 mA)**NOMINAL ANODE INPUT POWER**

648 W nominal at 81 kV, 8 mA

MAXIMUM TUBE CURRENT

3D imaging 10 mA, 0.01 s

Panoramic (Optional) imaging 8 mA

MAXIMUM ANODE OUTPUT POWER

900 W nominal at 90 kV, 10 mA

MAXIMUM GENERATOR OUTPUT POWER

3D maximum 900 W at 90 kVp, 10 mA

3D maximum nominal 210 W at 90 kVp, 10 mA

Panoramic (Optional) maximum 0.65 kW at 81 kVp, 8 mA

Panoramic (Optional) maximum nominal 0.65 kW at 81 kVp, 8 mA

REFERENCE CURRENT TIME PRODUCT

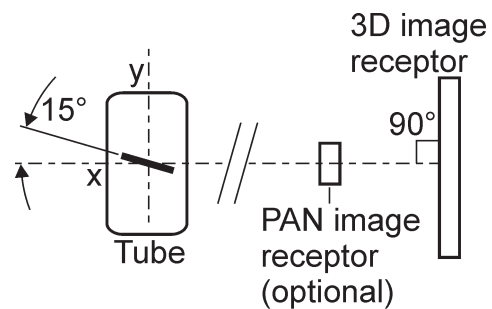
8 mAs at 81 kV, 8 mA, 1.0 s

FILTRATION - Collimator BLD-SBR3D-3

Total filtration:

- 3D 6.6 mm Al equivalent (0.2 mm Cu)

- Panoramic (Optional) 3.3 mm Al equivalent (0.1 mm Cu)



BEAM QUALITY

HVL over 3.2 mm Al at 85 kV

RADIATION LINEARITY

< 20%

PRIMARY PROTECTIVE SHIELDING

minimum 0.5 mm Pb or equivalent

OUTER SHELL TEMPERATURE

+50°C (122°F) maximum

DUTY CYCLE

Controlled by the software of the unit

3D, 28 pictures per hour

Panoramic (Optional), 19 pictures per hour

LEAKAGE TECHNIQUE FACTORS

3D

1680 mAs/h at 90 kV (FOV, 50 x 50 mm high resolution)

Panoramic (Optional)

81 kV, 2300 mAs/h (81 kV, 8 mA)

Power requirements**INPUT VOLTAGE**

230 - 240 VAC ($\pm 10\%$), 50/60 Hz single phase, grounded socket

LINE CURRENT

long term: 1 A (cont), 230 - 240 VAC mains

momentary: 8 A, 230 - 240 VAC mains

MAXIMUM LINE RESISTANCE

1 ohm

MINIMUM LINE FUSE

10 A slow at 230 - 240 VAC

LINE SAFETY SWITCH (when required)

Approved type, min. 10 A 250 VAC

EARTH LEAKAGE CIRCUIT BREAKER (when required)

Approved type, min. 16 A 250 VAC, breaker activation leakage current in accordance with local regulations.

Mains fuses (in the device)

F1 (special), 8 amp 250 V slow (6.3 x 32mm)

F2 (special), 8 amp 250 V slow (6.3 x 32mm)

External warning light fuse

F3 (special), 2 amp 250 V slow (6.3 x 32mm)

Mechanical parameters

SOURCE TO IMAGE LAYER DISTANCE (SID)

3D 650 mm (± 10 mm),Panoramic (Optional) 550 mm (± 10 mm)

MAGNIFICATION FACTOR

3D 1.5

Panoramic (Optional) 1.3

WEIGHT

308.6 kg, 313 kg with Panoramic (Optional)

DIMENSIONS

(H x W x D) 1963 x 1541 x 1100 mm

PATIENT HEIGHT

140 - 205 cm

PATIENT WEIGHT

maximum 150 kg

3D image receptor

TYPE

Amorphous silicon Flat Panel

Panoramic (Optional) image receptor

TYPE

CCD

PIXEL SIZE

48 microns

X-ray field size

3D

140 x 165 mm (Maximum), 50 x 50 mm (Minimum)

PANORAMIC (Optional)

Adult panoramic (maximum size) 15 cm x 30 cm

Timer

EXPOSURE TIMES

3D 6 s (maximum)

Panoramic (Optional) 15 s (maximum)

SINGLE LOAD RATING

81 kV, 8 mA, 15 s, panoramic

BACK-UP TIMER

30 s ($\pm 15\%$)**Measurement bases**

The kV is measured by monitoring differentially the current flowing through 450 Mohm, 1% feedback resistor connected between the tube anode and ground.

The mA is measured by monitoring current in the HT return line, which equals the tube current.

Collimator

PRIMARY SLIT

Motorized variable

Chair motor

DUTY-CYCLE

-Intermediate use: 6.25%, 25s ON, 400s OFF

Environmental data

OPERATING

- ambient temperature from +10°C to +30°C

- relative humidity 0 - 85% no condensation

STORAGE/TRANSPORTATION

- ambient temperature from 0°C to +50°C

- relative humidity 0 - 85% no condensation

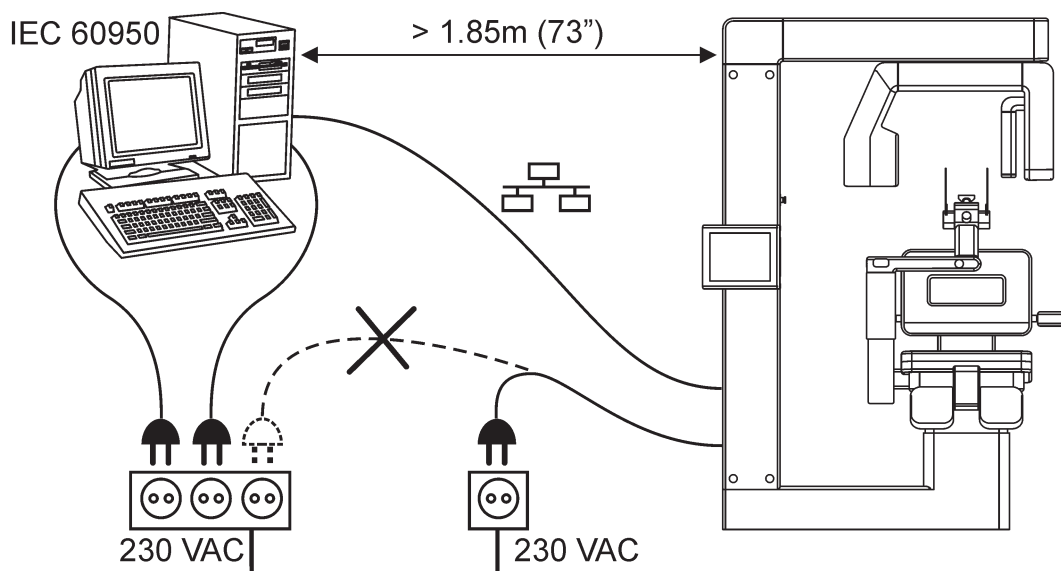
- atmospheric pressure 700 - 1060 mbar

PC requirements

- Windows 7 Professional/Ultimate/Enterprise SP1 (64-bit) or Windows Vista Business/Ultimate/Enterprise SP2 (64-bit)
- 2.5 GHz Intel quad core processor or AMD equivalent
- 4 GB RAM or more (6 - 8 GB recommended)
- 1000 GB (1 Terabyte) 7200 RPM HDD or better (RAID 1 strongly recommended)
- DVD-ROM drive
- Two 1000 Mb/s Gigabit Ethernet ports
- One available PCI-Express x16 bus slot for supplied GPU card (full length, dual slot)
- 2 available USB ports (hardware keylocks)
- 20" LCD display, 1600 x 1200 pixels, 32 bit color
- 500 watt power supply with two 6-pin PCIe supplementary power cables
- The PC must meet the IEC 60950 standard (minimum requirements)

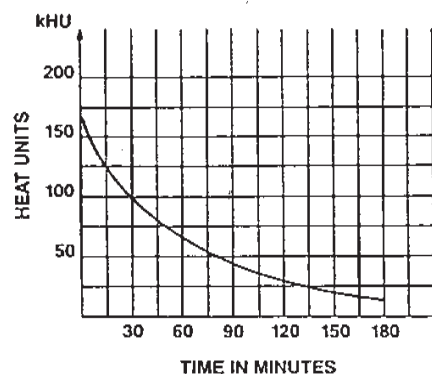
System requirements and connections

- The PC and any other external device(s) connected to the system must meet the IEC 60950 standard (minimum requirements). Devices that do not meet the IEC 60950 standard must not be connected to the system as they may pose a threat to operational safety.
- The PC and any other external devices must be connected in accordance with IEC 60601-1-1.
- The x-ray unit must be connected to its own separate power supply. The PC and any other external devices must NOT be connected to the same power supply as the x-ray unit.
- Position the PC and any other external device at least 1.85 m (73") from the x-ray unit so that the patient cannot touch the PC or any other external device while being x-rayed.
- The PC and any other external devices shall not be connected to an extension cable.
- Multiple extension cables shall not be used.
- Do not position the PC where it could be splashed with liquids.
- Clean the PC in accordance with the manufacturer's instructions.

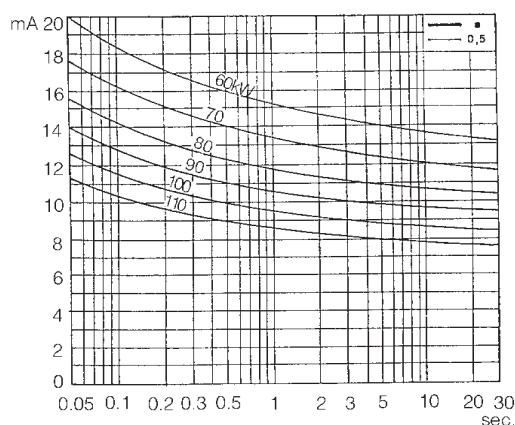


Tube housing assembly cooling/heating characteristics

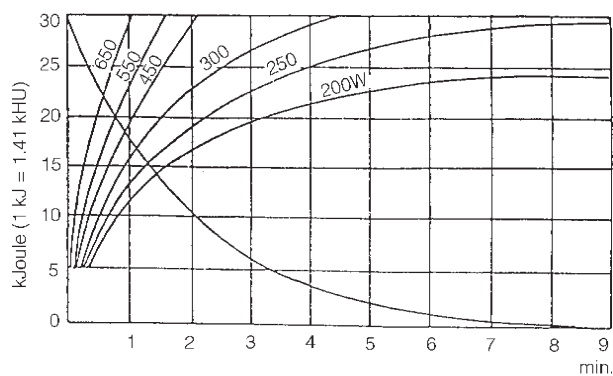
TUBE HOUSING ASSEMBLY COOLING CHARACTERISTICS



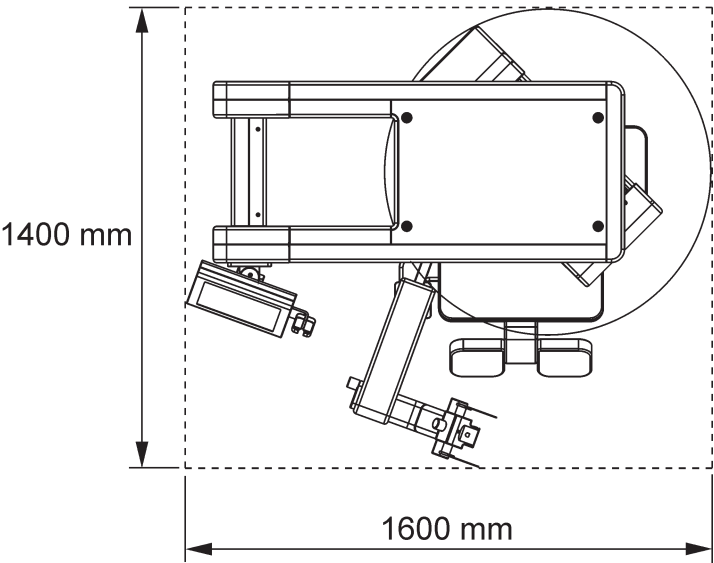
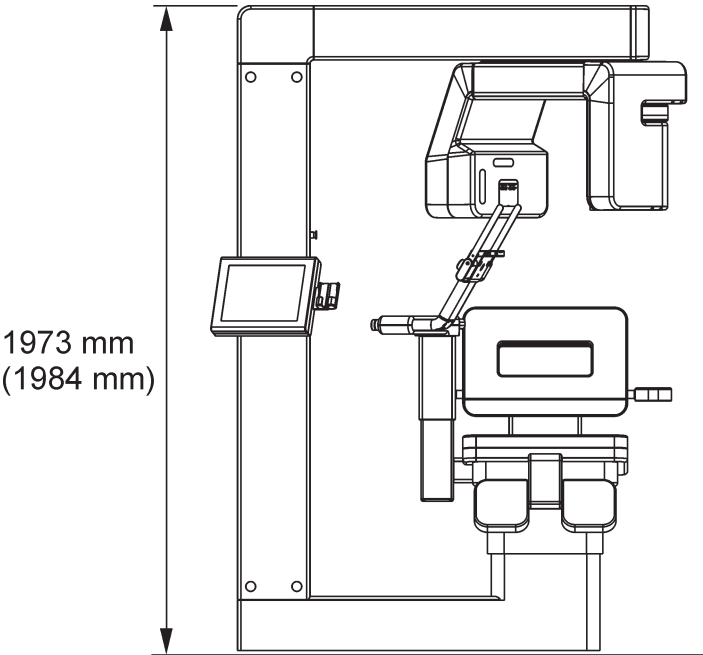
Tube rating chart



Anode thermal characteristics




A.2 Unit dimensions



A.3 Electromagnetic declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The SBR3D-2 is intended for use in the electromagnetic environment specified below. The customer or the user of the SBR3D-2 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The SBR3D-2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B + 12	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	The SBR3D-2 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity			
The SBR3D-2 is intended for use in the electromagnetic environment specified below. The customer or the user of the SBR3D-2 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients/bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If user of the SBR3D-2 requires continued operation during power mains interruptions, it is recommended that the SBR3D-2 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The SBR3D-2 is intended for use in the electromagnetic environment specified below. The customer or the user of the SBR3D-2 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the SBR3D-2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$ <p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SBR3D-2 is used exceeds the applicable RF compliance level above, the SBR3D-2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SBR3D-2.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the SBR3D-2.

The SBR3D-2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SBR3D-2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SBR3D-2 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.